

# EXHIBIT B

REDACTED

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN JOSE DIVISION**

**TEVRA BRANDS, LLC,**

Plaintiff,

v.

**BAYER HEALTHCARE LLC, and  
BAYER ANIMAL HEALTH GmbH, and  
BAYER AG,**

Defendants.

Case No. 3:19-cv-04312-BLF

**EXPERT REPORT OF DR. PAUL WONG**

9 August 2023

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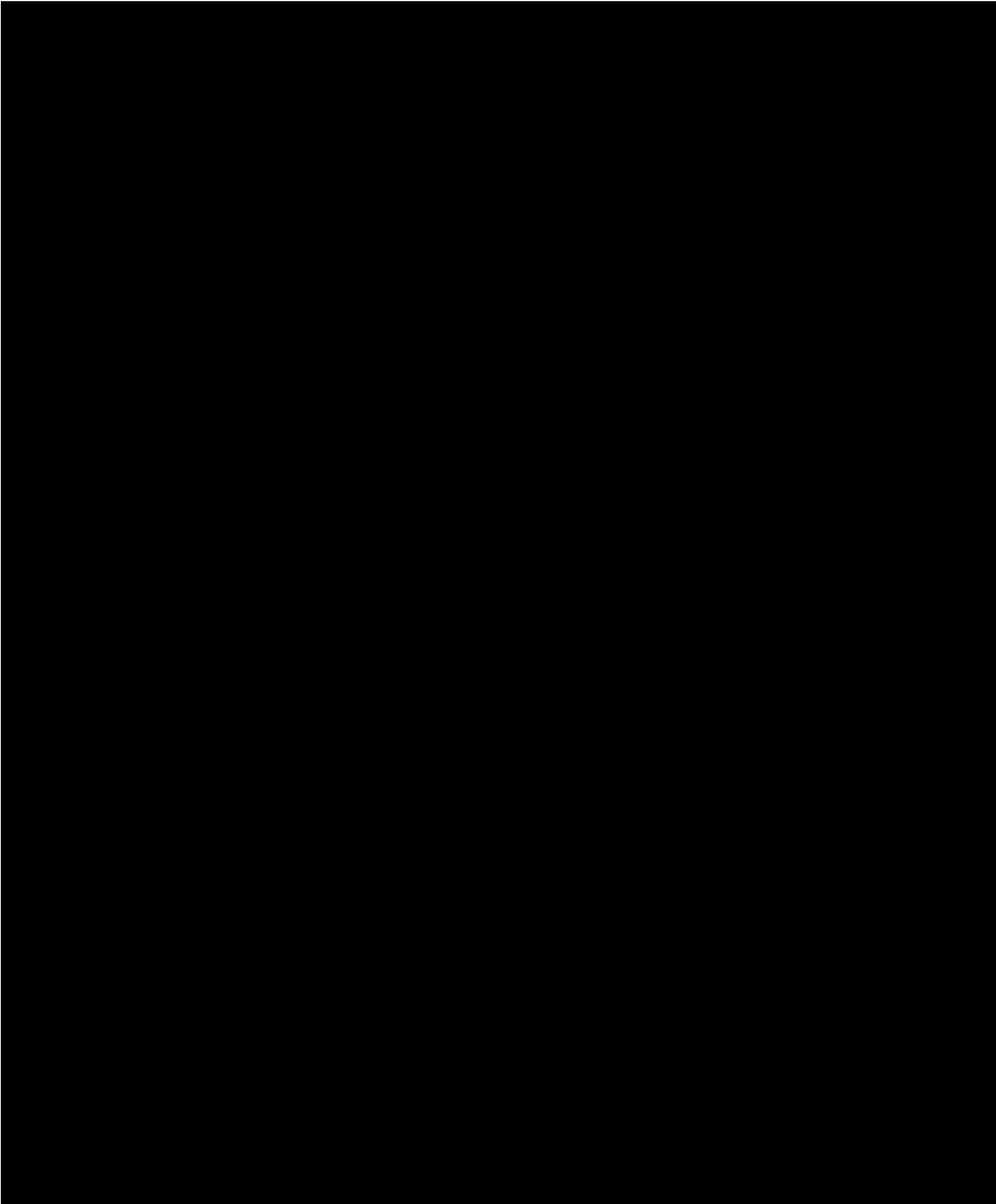
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## **I. Introduction**

### **A. Qualifications**

1. I am an economist and a Managing Director at NERA Economic Consulting. NERA is a global firm of experts dedicated to applying economic, finance, and quantitative principles to complex business and legal issues. I received my Ph.D. and M.A. in Economics from Stanford University, and my B.A. in Business Economics from the University of California Los Angeles (UCLA). Prior to joining NERA, I have experience in healthcare services research and healthcare analytics from my work at Palo Alto Medical Foundation Research Institute, and experience as an investment manager from my work at Brandes Investment Partners. I have also taught economics at the Anderson Graduate School of Management at the University of California Riverside (UCR).

2. My areas of expertise are in the economics of antitrust, competition, industrial organization, and healthcare. I have written a number of articles and have been asked to speak numerous times on issues and topics involving competition, particularly in healthcare markets. I have also worked on a variety of litigations in healthcare and antitrust, and I have advised on numerous high-profile hospital mergers.

3. My publications and engagements are listed in my curriculum vitae, which is appended to this report as **Exhibit 1**. I have conducted academic research on a variety of healthcare and antitrust issues and published articles in journals such as *Population Health Management*, *Loyola University Chicago Law Journal*, and *Competition*. In addition, I have presented to a number of organizations, including the U.S. Department of Justice, the American Society of Health Economists, the American Health Lawyers Association, the American Bar Association, and the State of Indiana's legislature.

### **B. Assignment**

4. Counsel for Plaintiff, Tevra Brands ("Tevra"), has asked me to review the claims in this matter and opine on them and other economic concepts as may be relevant to this matter. My initial opinions are explained in detail throughout this report.

5. Because expert discovery is ongoing, I may supplement or refine my opinions as warranted by any relevant new information, new allegations by Plaintiff, and analyses or opinions by Defendants' expert(s). While my opinions are preliminary in that sense, they are



based on the extensive information and data I have already reviewed and analyzed, so I do not expect these opinions to change materially.

6. NERA's compensation for my time is currently \$810 per hour. Similarly, NERA's compensation for my staff's time is at standard hourly rates. No payments to NERA are contingent upon the outcome of this case or upon the nature of my opinions.

### C. Understanding of Claims

7. Plaintiff's allegations, as they concern my economic analysis in this report, are summarized as follows.

8. Defendants, collectively and individually the "Bayer"<sup>1</sup> companies, sell flea and tick treatments for pets, among a variety of animal health products. Bayer's key product lines within the flea and tick treatment space are: (a) topical "spot-on" ointments containing the chemical imidacloprid, marketed under the brand names "Advantage" and "Advantix" ("Advantage/Advantix"<sup>2</sup>); and (b) flea collars also containing the chemical imidacloprid, marketed under the brand name "Seresto."<sup>3</sup> The chemical imidacloprid was developed as an insecticide for agriculture, and as a "spot-on" ointment for pets it is effective at killing and repelling fleas in both the adult and larval stages.<sup>4</sup>

9. Bayer's Advantage/Advantix products were first introduced in the late 1990s, and between their introduction and approximately 2016 they were essentially the only topical imidacloprid treatments sold in the United States.<sup>5</sup> Over that period, Bayer had various intellectual property protections, including at least one patent related to its topical imidacloprid products and exclusivity on its EPA registration.<sup>6</sup>

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<sup>1</sup> Throughout this report, I will use the term "Bayer" to refer to the various Bayer companies generally, both individually and jointly. For the most part, my economic analysis and opinions do not distinguish between the different Bayer affiliates or subsidiary companies, nor do they need to—consistent with standard economic theory—as it is assumed that the Bayer companies acted economically as one integrated firm. That said, if a particular Bayer company must be identified or distinguished individually for any of my analysis or opinions, I will endeavor to make that clear where necessary.

<sup>2</sup> There have been multiple versions of the Advantage and Advantix products over time, including Advantage, Advantix, Advantage II, Advantix II, Advantage Multi, and others. Advantix products include permethrin in addition to imidacloprid, which kills and repels ticks, mosquitoes, and biting flies but causes toxicity in cats. The different versions of Advantage/Advantix products have differed in some of their active ingredients, but they all rely on imidacloprid as their main active ingredient. For example, Advantage contained only imidacloprid, and Advantage II adds pyriproxyfen in addition to imidacloprid.

<sup>3</sup> Second Amended Complaint, *Tevra Brands, LLC, v. Bayer Healthcare LLC, and Bayer Animal Health GmbH*, No. 3:19-cv-04312-BLF, filed March 29, 2021 ("SAC"), ¶¶ 2 and 74.

<sup>4</sup> SAC, ¶¶ 63 and 66.

<sup>5</sup> See, *infra*, Exhibit 3A.

<sup>6</sup> SAC, ¶ 87.

10. Around late 2016, as Bayer’s various intellectual property protections expired, “generic” topical imidacloprid products attempted to enter the market.<sup>7</sup> As with generic products generally, these products were intended to be low-cost equivalents to the “branded” Advantage/Advantix products, offering essentially the same product at a substantially lower price.<sup>8</sup> Tevra was one of two main generic entrants, and it attempted to market its generic topical imidacloprid product line called Activate/Avantect.<sup>9</sup> In some of its first sales efforts, Tevra approached the main retailers of topical imidacloprid products, including large pet specialty retailers and distributors, like Petco and PetSmart, and large e-commerce pet retailers, like Chewy.com.<sup>10</sup>

11. Tevra alleges that it was rebuffed by these retailer and distributor customers—Tevra was and still is unable to sell to many of these customers.<sup>11</sup> Tevra alleges that its inability to sell to these customers is because Bayer had agreements and/or signed exclusive, exclusionary contracts with the majority of these customers, and these contracts forbid the customers from offering for retail sale (and thereby purchasing at the wholesale level) generic topical imidacloprid products like Tevra’s that compete with Bayer’s own Advantage/Advantix products.<sup>12</sup> Tevra contends that these contracts and agreements had the intent and effect of significantly foreclosing competition from Tevra and other generic topical imidacloprid products, allowing Bayer to maintain its own prices and sales quantities at higher levels than it otherwise could have and, ultimately, harming U.S. consumers by depriving them of important lower-cost products.<sup>13</sup>

12. Tevra alleges that Bayer’s exclusionary contracts—and their success in foreclosing generic competition—allowed Bayer to maintain its pre-existing monopoly in the relevant market for topical imidacloprid treatments in the United States. As evidence of Bayer’s ongoing monopoly, Tevra alleges that (a) Bayer continues to hold a dominant market share in the

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<sup>7</sup> SAC, ¶ 88.

<sup>8</sup> SAC, ¶¶ 1 and 100.

<sup>9</sup> SAC, ¶ 3. Tevra also sells products under the name “Actisport.” For brevity, I use the term “Activate/Avantect” to refer generally to Tevra’s imidacloprid spot-on products.

<sup>10</sup> SAC, ¶ 135.

<sup>11</sup> SAC, ¶ 106.

<sup>12</sup> SAC, ¶¶ 159-164.

<sup>13</sup> SAC, ¶ 171.

relevant market and the relevant market exhibits significant barriers to entry, and (b) Bayer charges supracompetitive prices.<sup>14</sup>

13. Tevra seeks damages to compensate for its lost sales and profits as a result of Bayer's alleged exclusionary conduct.<sup>15</sup> But for Bayer's conduct, Tevra alleges it would have made significantly more sales of its Activate/Avantect products, causing it to lose approximately \$100 million in profits.<sup>16</sup>

#### **D. Materials Relied Upon**

14. The opinions in this report are based on my professional training and experience, as well as on my review of Tevra's complaint in this matter, data and documents produced in the course of discovery, and information from publicly available sources. A complete list of the materials and information that I relied upon to prepare this report is attached as **Exhibit 2**. Many of the footnotes in this report also cite to these materials.

## **II. Summary of Opinions**

15. It is my expert opinion that Tevra's core allegations against Bayer, as generally summarized above, are correct as a matter of economics and are well supported by economic theory and the economic evidence in this case. Bayer monopolized the relevant antitrust market for topical imidacloprid spot-on products up to 2016. From that point, Bayer employed anticompetitive exclusive contracts with wholesale customers that foreclosed generic competitors, including Tevra, thereby allowing Bayer to maintain its sales quantities, increase prices, and support its dominant market position. Because of Bayer's contracts, Tevra was (and still is) unable to sell to these wholesale customers, depriving the market of important competition, Tevra of lost sales, and consumers of significant savings.

16. In this report, I present an analysis of the history of the flea and tick treatment industry from 2010 to the present which confirms Tevra's allegations (*see Section III.A.2*). My analysis shows that—up to the 2010 to 2011 timeframe—there were two main “branded” spot-on flea and tick treatments: Bayer's Advantage/Advantix products, containing the chemical

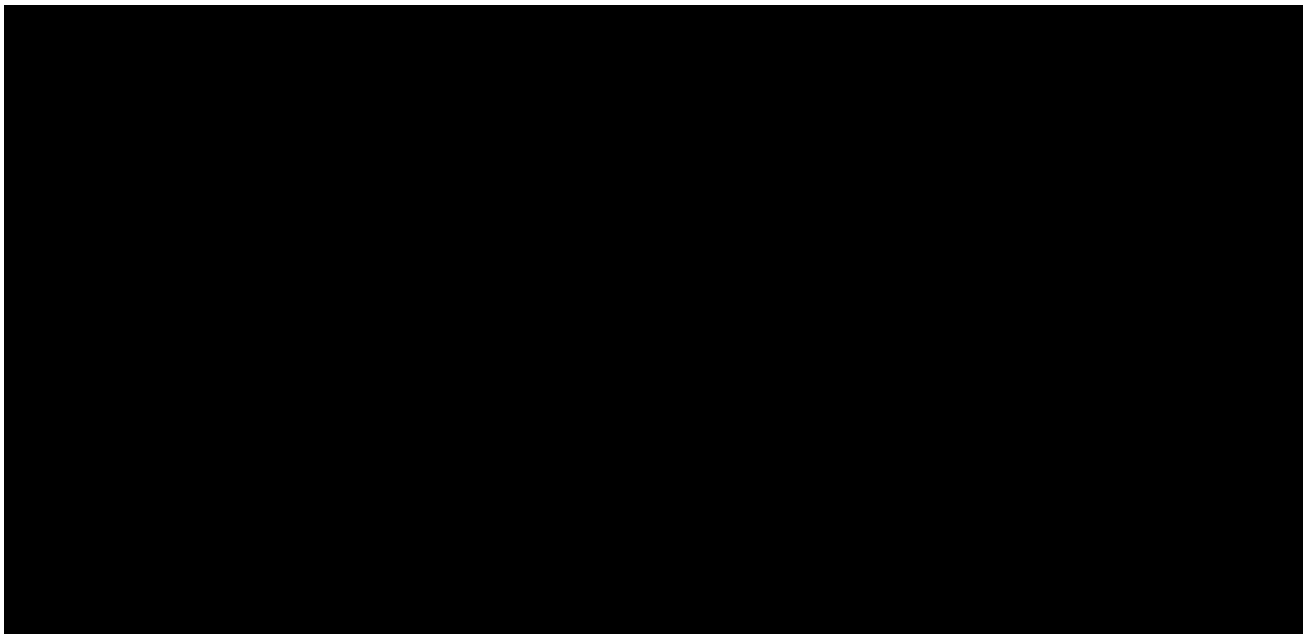
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<sup>14</sup> SAC, ¶ 3.

<sup>15</sup> SAC, ¶¶ 222, 227, and 233.

<sup>16</sup> SAC, ¶ 215.

imidacloprid, and Merial's Frontline products, containing the chemical fipronil. After that point, multiple generic versions of Frontline (i.e., generic fipronil spot-ons) entered and eventually captured almost half of Frontline's annual sales by 2016 and later. *However*, over the same course of time, Bayer's Advantage/Advantix did not respond significantly to that or any other sources of competition—to wit, Bayer's sales actually grew slightly from 2010 to 2016 despite increasing competition in the industry generally. This comparison between Frontline and Advantage/Advantix presents a key “natural experiment” that (a) confirms the relevant market is appropriately limited in this case to only imidacloprid spot-ons, (b) shows Bayer's monopolization and monopoly power in that relevant market for imidacloprid spot-ons, and (c) quantifies the impact of Bayer's anticompetitive conduct, including Tevra's lost sales as a foreclosed generic competitor and excess expenditures by U.S. consumers. The contrast between the history of Frontline (red line) and the history of Advantage/Advantix (blue line) is clearly summarized in this diagram plotting sales quantities over time, as reproduced from **Exhibit 7A**.



17. Well-accepted public policy and economic theory agrees that branded pharmaceuticals—like Advantage/Advantix and Frontline—should eventually see significant substitution to generic competitors and significant loss of sales versus their pre-generic-entry baseline (*see* **Section III.B**). This substitution is a key driver of ongoing savings to end consumers and is well documented in countless pharmaceutical cases. Crucially for this case, the textbook economic theory is illustrated in Frontline's own history—Frontline's loss in sales (a) is consistent with what economic theory expects, (b) shows what sales generic competitors ought to

win by offering lower prices, and (c) is the exact motivation Bayer executives themselves documented contemporaneously when Bayer began its anticompetitive strategy. Simply put, Frontline’s history shows what is supposed to happen when there is an “even playing field” for competition in the flea and tick treatment industry—the branded product should see a 50% or more decline in sales as substitution moves demand to lower-priced generic competitors (*see Exhibits 7A-7B*).

18. [REDACTED]

[REDACTED]

19. That history and the stark comparison between Advantage/Advantix and Frontline confirms that the relevant antitrust market is appropriately limited to only imidacloprid spot-ons sold to U.S. wholesale customers. In short, the comparison between Advantage/Advantix and Frontline provides a setting that almost perfectly recreates a “hypothetical monopolist test,” as

outlined in the federal antitrust agencies' *Horizontal Merger Guidelines* (see **Section IV.A**). From 2010 to 2016, Bayer was an actual monopolist in the market for imidacloprid spot-ons—it had government-sanctioned exclusivity owing to its patents and exclusive registration with the EPA. And during that time, Bayer increased its prices by a significant, non-transitory amount (a “SSNIP”; see **Section IV.C.2.a**) without losing sales or experiencing decreased profits, and without any significant substitution toward other flea and tick treatment products (see **Section IV.C.2.b**). In contrast, over the same period, Frontline's sales declined as demand substituted toward generic fipronil spot-ons. Bayer's success as the actual (and hypothetical) monopolist of the imidacloprid spot-on market, and the clear, significant losses documented in Frontline's history show that (a) the relevant market is appropriately limited to only imidacloprid spot-ons and (b) all other products, including fipronil spot-ons, are appropriately excluded, as both individually and collectively these other products were insufficient to defeat Bayer's SSNIP.

20. In the relevant market for imidacloprid spot-ons, Bayer has and continues to hold monopoly power. This is demonstrated by both indirect and direct methods (see **Section V.A**). First, indirectly, Bayer has and continues to hold a high market share and the relevant market exhibits significant barriers to entry—both economic facts are necessary conditions for showing a firm holds monopoly power (see **Section V.B**). Second, directly, Bayer charges supracompetitive prices for its Advantage/Advantix products, as is clear from its significant price increases in both absolute and relative terms (see **Section V.C**). Most notably, as noted above, Bayer increased its price by a SSNIP in the face of both increasing competition from fipronil spot-ons until 2016, and Bayer has increased its price still further after 2016 despite attempts to enter and expand by generic imidacloprid spot-ons. Finally, Bayer's market position and prices have been successfully maintained versus what should have transpired (see **Section V.D**). As noted just above, Bayer's price increases have well exceeded Frontline, and yet Bayer's decline in sales has been less than half of what Frontline experienced as sales substituted toward generic competitors.

21. Bayer clearly understood the risk to its significant pre-2016 market position, the applicability of Frontline's history, and the economics underlying branded versus generic

pharmaceutical competition.<sup>17</sup> Fearing a similar fate to Frontline, Bayer set out on a multifaceted strategy to “block generic entry,” thereby allowing Bayer to maintain its prices and market position after 2016 despite competition by generic imidacloprid spot-ons. The key pillar of Bayer’s anticompetitive strategy was a series of exclusive contracts with large wholesale customers (*see Section VI*). These contracts prevent wholesale customers from purchasing (and thereby offering at retail) generic imidacloprid products, allowing Bayer to sidestep head-to-head competition from generic competitors and preventing consumers from “trading down” to cheaper but equivalent products. Thus, Bayer’s contracts foreclosed generic competitors, like Tevra, and harmed competition, reducing the downward pricing pressure faced by Bayer and propping up its sales quantities, causing consumers to ultimately pay significantly more than they should have. Moreover, Bayer’s own documents outline the economic theory supporting their anticompetitive scheme—by providing an exclusivity discount, Bayer could incentivize wholesale customers to go along with Bayer’s anticompetitive scheme, both contrary to customers’ typical practices and to the benefit of the wholesale customers despite the detriment to retail consumers (*see Section III.C.2*). To wit, the same customers illustrate the stark comparison between Frontline and Advantage/Advantix—those customers exclusively offer Bayer’s imidacloprid spot-ons—to the exclusion of generic imidacloprid competitors—and yet they offer both Frontline and generic fipronil spot-ons.

22. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

23. Using Frontline’s history as an example of the but-for world, I calculate that Bayer should have lost—and Tevra should have correspondingly gained—sales quantities of approximately 37 million doses from 2017 to 2023 (*see Exhibit 12A*). At Tevra’s sales prices, these 37 million additional doses would have resulted in \$185 million in sales over those seven years. Independently verifying a similar effect, Tevra’s actual performance compared to its pre-entry forecasts show a \$173 million shortfall over the same period (*see Exhibit 12B*). Based on Tevra’s historical profit margins, those lost sales of \$173 to \$185 million should have translated into \$84 to \$109 million of profits (*see Exhibits 13A-13B*). Furthermore, those same \$173 to \$185 million in incremental sales by Tevra—at significantly lower prices than Bayer—would have saved consumers \$195 to \$214 million in retail expenditures (*see Exhibit 14*). Thus, Bayer’s anticompetitive conduct caused significant harm to both Tevra, as a lower-priced generic competitor, and to consumers across the United States.

### III. Background

24. In this section, I discuss some of the main industry facts and general economic theories that are important for my analysis in this case.

#### A. The Pet Medicine Industry

25. This case involves pharmaceutical products ultimately sold to (human) consumers. The main difference between this case and many other pharmaceutical cases is that this case involves pharmaceuticals administered to animals—namely, “companion animals” (i.e., cats and dogs kept as pets).<sup>18</sup> Whereas, in most pharmaceutical cases consumers nominally purchase pharmaceutical products for use on themselves, here the case involves consumers ultimately purchasing pharmaceutical products to administer to their pets. In this subsection, I discuss the main industry facts that make this case somewhat unique.

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<sup>18</sup> There are many types of animal pets beyond cats and dogs, such as birds, small reptiles, small rodents, and others. For this report, I use the term “pet” as synonymous with cats and dogs, which are by far the most frequent types of pets in the U.S. and account for essentially all of the demand for flea and tick treatments.



## 1. Demand for Flea and Tick Treatments

26. Roughly half of U.S. consumers own pets, and pet ownership has and continues to grow steadily from about 59 million U.S. households (50% of all households) in 2008, to about 68 million U.S. households (52%) in 2022.<sup>19</sup> This substantial pet ownership, in turn, drives substantial and steadily growing demand for pet pharmaceutical products—total pet spending on all products grew roughly 8% per year between 2010 and 2021 (reaching \$123 billion), and spending on pet medicines has consistently accounted for one-tenth of overall spending (reaching about \$12.6 billion as of 2021).<sup>20</sup>

27. Flea and tick treatments account for a large subset of the roughly \$10-plus billion per year demand for pet medicines. Retail databases (discussed later) suggest flea and tick treatments account for roughly \$3 billion per year in spending (roughly one-quarter to one-third of pet medicine spending).<sup>21</sup> Further, available evidence suggests demand for flea and tick treatments has grown steadily and continuously, in-line with the growth in demand for pet medicines and pet products generally.<sup>22</sup>

28. Within a year, demand for flea and tick treatment is highly seasonal, with demand low in the winter, growing throughout the spring and summer, and returning from the summer peak through the fall.<sup>23</sup> Across years, however, demand for flea and tick treatments is predictable and shows steady-moving trends.<sup>24</sup>

## 2. Available Flea and Tick Treatments

29. There are presently seven main categories of flea and tick treatments sold in the United States:

- a) Imidacloprid topical “spot-on” products (namely, Bayer’s Advantage/Advantix and generic formulations, like Tevra’s Activate/Avantect);

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<sup>19</sup> PetIQ, 2017 10-K, p. 4; PetIQ, 2022 10-K, p. 5.

<sup>20</sup> PetIQ, 2022 10-K, p. 5.

<sup>21</sup> See, *infra*, **Exhibit 3C**.

<sup>22</sup> PetIQ, 2017 10-K, p. 4; PetIQ, 2022 10-K, p. 5. For example, oral flea and tick treatments grew from approximately 66 million doses in 2016 to 100 million doses by 2019.

<sup>23</sup> See, e.g., Bayer’s wholesale data shows monthly sales quantities that grow steadily in the first and second quarters of the year and gradually taper off thereafter, with the lowest quantities in the fourth quarter of the year.

<sup>24</sup> See, *infra*, **Exhibits 3B and 3C**. For this reason, my baseline analyses look at annual trends where possible. Where partial years are analyzed and/or compared to other annual numbers, I annualize and make efforts to seasonally adjust the data to account for differences in demand across times of the year.

- b) Fipronil topical “spot-on” products (namely, Frontline and its various generic formulations);<sup>25</sup>
- c) Topical “spot-on” products with other active ingredients (e.g., permethrin, natural oils, etc.);
- d) Flea collars (namely, Bayer’s Seresto);
- e) Orally administered flea and tick drugs (namely, NexGard, Bravecto, and Simparica);
- f) De-wormer “combo” products (i.e., treating worms *and* fleas and ticks; namely, Revolution, Sentinel, and Trifexis); and
- g) A collection of other products that are generally not longer-lasting treatments but provide some temporary treatment, including shampoos and sprays.

**Exhibit 3A** lists the main products across these categories and summarizes the approximate entry dates of the popular flea and tick treatments, based on EPA and FDA approval dates (explained later) where known.

30. Up until approximately 2010 there were more limited choices for flea and tick treatments for U.S. consumers. Primarily, the most popular choices at the time were:

- a) Bayer’s branded Advantage/Advantix spot-ons:
  - i) Introduced in the late 1990s to early 2000s,
  - ii) Primary active ingredient imidacloprid,
  - iii) Sold mainly through pet specialty retailers;<sup>26</sup>
- b) Merial’s<sup>27</sup> branded Frontline spot-ons:
  - i) Introduced in the early 2000s,
  - ii) Primary active ingredient fipronil,

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<sup>25</sup> Fipronil, like imidacloprid, was formulated as an agricultural insecticide. It is effective in killing adult fleas when used as a spot-on treatment, but it has limited resistance to water, and some studies have suggested its efficacy against certain strains has lessened in recent years. *See, e.g.,* Dryden, M. W. et al., “Evaluation of Indoxacarb and Fipronil (s)-Methoprene Topical Spot-on Formulations to Control Flea Populations in Naturally Infested Dogs and Cats in Private Residences in Tampa FL, USA,” *Parasites Vectors*, Vol. 6, No. 1, 2013, pp. 366-372.

<sup>26</sup> *See, infra*, **Exhibit 4A**.

<sup>27</sup> I refer to Frontline’s manufacturer as Merial, as that was its original manufacturer when it was introduced. Since then, Merial has been acquired by Boehringer Ingelheim. Similarly, Bayer has recently been acquired by Elanco, and many of the other products discussed in this report have changed companies through M&A. For the most part, I try to use a single manufacturer name for each branded product for consistency of reference—across time, the actual manufacturer may have been different or changed, but this should not affect the economic analysis below.

- iii) Initially sold mainly by vets, but increasingly sold by pet specialty retailers and general retailers;<sup>28</sup>
- c) Other chemical spot-ons:
  - i) Introduced in the late 1990s and 2000s,
  - ii) Primary active ingredients other than imidacloprid and fipronil,
  - iii) Sold mainly through general retailers;<sup>29</sup>
- d) De-wormer “combo” products:
  - i) Introduced in 2011 and earlier,
  - ii) A combination of multiple main active ingredients,
  - iii) Sold mainly through the veterinary sales channel<sup>30</sup> and only by prescription,
  - iv) Sold at significantly higher prices than other flea and tick treatments without a “combo” worm treatment;<sup>31</sup>
- e) A variety of other “legacy” products, such as flea collars, sprays, and shampoos:
  - i) Active ingredients other than imidacloprid and fipronil,
  - ii) Sold mainly through retail channels including pet specialty stores and general merchandisers.

Although comprehensive sales data for that early point does not exist in the record for this case to my knowledge, the available data suggest Advantage/Advantix and Frontline accounted for a large percentage of the flea and tick treatments sold.<sup>32</sup>

31. [REDACTED]

<sup>28</sup> See, *infra*, **Exhibit 4A**.

<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

<sup>31</sup> See, *infra*, **Exhibit 3C**.

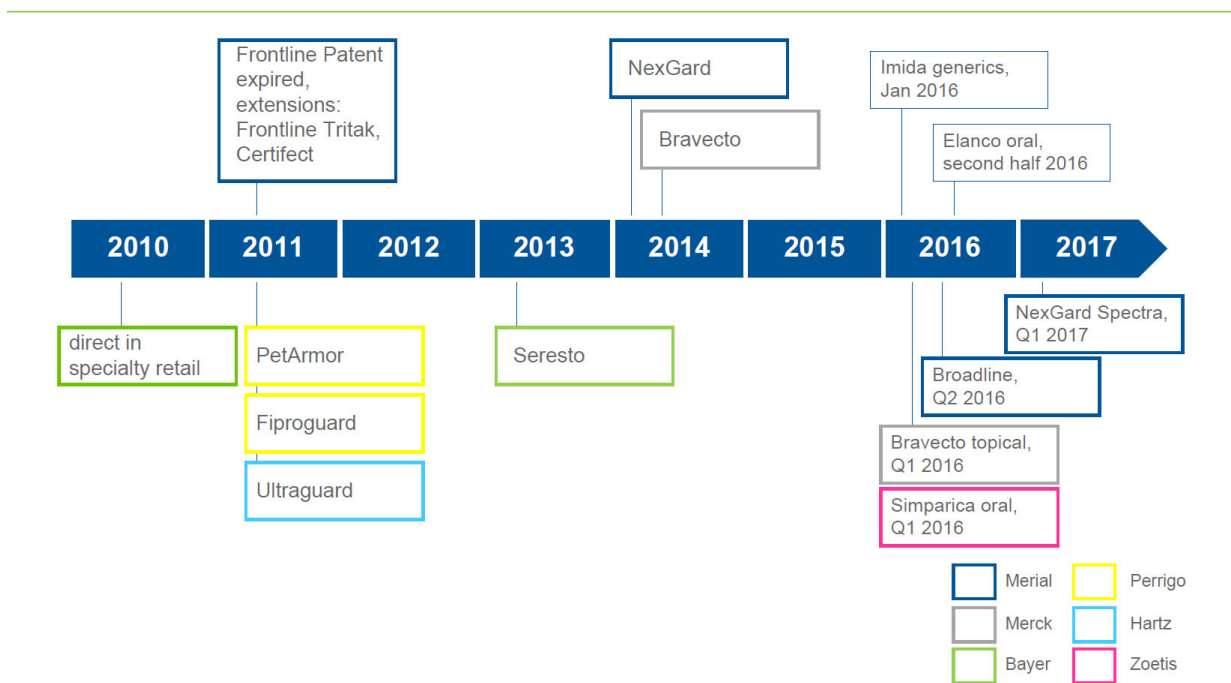
<sup>32</sup> See, *infra*, **Exhibits 3B and 3C**. The available data suggest Advantage/Advantix and Frontline likely accounted for more than roughly one-third of all flea and tick treatments at the time, since Advantage/Advantix and Frontline were roughly 110 million doses in 2010 and the total dosage sold was likely less than the roughly 320 million doses as of 2016.

<sup>33</sup> BAH000050845, p. 11; Scott Bauer (Bayer) deposition, 12/14/2022 (“Bauer deposition”), pp. 218:8–14.

b)

Many new products will hit the market in the near future along with imidacloprid generics

Major US F/T Product Launches and Developments



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32. Later, other now-popular flea and tick treatments were introduced, including:

a) Bayer's branded Seresto collar:

- Introduced in 2013,
- Primary active ingredient imidacloprid,
- Steadily increasing sales from 2013 to 2020,

<sup>34</sup> *Id.*

<sup>35</sup> *Id.*

- d. Recent debate concerning the safety of this product;<sup>36</sup>
- b) Various oral treatments, including NexGard, Bravecto, and Simparica:
  - a. Introduced mostly in 2013 to 2016,
  - b. Sold almost exclusively by prescription,
  - c. Sold almost exclusively through the veterinary sales channel,
  - d. Sold at significantly higher prices than spot-on flea and tick treatments.<sup>37</sup>

Importantly, much of the success of Seresto and oral products occurred in 2016 or later, as is illustrated in Bayer's ordinary course documents.<sup>38</sup>

33. Most relevant to this case, despite the course of these industry changes, overall demand for imidacloprid and fipronil spot-on products has stayed relatively constant. **Exhibit 3B** shows the estimated quantity of spot-ons sold using the available data. As of 2010, wholesale data for Advantage/Advantix and Frontline show 110.5 million doses sold (i.e., the standardized quantity measured as the number of treatments sold covering one pet for one month).<sup>39</sup> Assuming essentially zero sales of other spot-on products in 2010, as this date pre-dates the vast majority of entry by other notable spot-on products, this 110.5 million doses number is a reasonable estimate of the baseline demand for spot-ons at that point. As of 2016, the first data point for which comprehensive data are available, there were an estimated 100.4 million doses sold for imidacloprid and fipronil spot-ons, and another estimated 34.6 million doses sold for other chemical spot-ons (135.0 million in total across all chemicals). Thus, from the 2010 baseline, demand was relatively flat for imidacloprid and fipronil spot-ons through at least 2016, and it potentially grew moderately if one includes other chemical spot-ons.<sup>40</sup> As is discussed later, this trend is important economic evidence showing there is (a) dedicated, predictable demand for spot-on flea and tick treatments and (b) within spot-on flea and tick treatments, generally, there is dedicated, predictable demand for imidacloprid products—of which,

<sup>36</sup> "EPA Requires Additional Mitigation Measures for Seresto Pet Collars," United States Environmental Protection Agency, 7/13/2023, <https://www.epa.gov/pesticides/epa-requires-additional-mitigation-measures-seresto-pet-collars> (accessed 8/4/2023).

<sup>37</sup> See, *infra*, **Exhibit 3C**.

<sup>38</sup> BAH000050845, p. 11; BAH000257075, pp. 7 and 38.

<sup>39</sup> The standardized measure of quantity—monthly doses—facilitates a consistent comparison across time and products. And it facilitates a standardized measure of price—price per monthly dose—which measures the cost to acquire one month's treatment for one pet. Where possible, I compare across time and products using these standardized units of measure.

<sup>40</sup> Since data on other chemical spot-ons are not available as of the 2010-2011 timeframe, I cannot directly compute a growth rate. Still, given the general industry trend towards growth, it seems reasonable that spot-on demand grew slightly in light of the available data.

Advantage/Advantix account for nearly all of the sales to-date. As the table also shows, demand for imidacloprid spot-ons specifically exceeded an estimated 37 million doses in every year from 2010 to 2018, with Advantage/Advantix accounting for more than 85% of those doses in each year.

34. The available data surveying the total overall annual amount of flea and tick treatments sold from 2016 to 2019 is shown in **Exhibit 3C**. Based on retail sales, there are over \$3.6 billion in sales and over 314 million doses sold per year. Of that overall demand, based on doses each year, spot-ons account for about 21% to 29%, collars account for about 19% to 23%, orals account for about 21% to 32%, combo products account for about 12% to 19%, and other products (e.g., shampoos, etc.) account for about 12%. The data also show that the different product types generally sell at different retail price points, with oral and combo de-wormer products selling at the highest prices, collars and other products selling at the lowest prices, and spot-ons selling in between based on a standardized measure of price per dose.

### **3. Government Registration of Flea and Tick Treatments**

35. Essentially all of the major flea and tick products discussed above use a pesticide or drug for their active ingredient. Because of this, these products are highly regulated, requiring government registration, safety studies and/or clinical trials, and ongoing regulations and restrictions concerning their sale and distribution. These government regulations are an important barrier to entry for new competitors—they account for significant, costly investments that firms must make in order to sell their flea and tick products in the United States.

36. In most cases, the EPA regulates spot-on, collar, and many other flea and tick treatment products because they contain regulated pesticides.<sup>41</sup> Products must initially be registered with the EPA and are then (once approved) subject to ongoing requirements (e.g.,

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<sup>41</sup> “EPA’s Regulation of Flea and Tick Products,” United States Environmental Protection Agency, <https://www.epa.gov/pets/epas-regulation-flea-and-tick-products> (accessed 8/4/2023); “EPA’s Evaluation and Regulation of Pet Collar Products,” United States Environmental Protection Agency, <https://www.epa.gov/pets/epa-evaluation-and-regulation-pet-collar-products> (accessed 8/2/2023).

labeling<sup>42</sup>) and regulation (e.g., ongoing safety reporting<sup>43</sup>). The initial registration requires an extensive submission of data and analysis showing efficacy and safety of the product.<sup>44</sup> For products with “new chemicals” or “new active ingredients,” applicants for registration must typically commission costly research studies.<sup>45</sup> Successful “new” product registrants are rewarded for their efforts and investments with 10 years of exclusive use of the data submitted in their registration application (“exclusive data rights”).<sup>46</sup> For products with “substantially similar or identical” chemicals or active ingredients to those already approved, applicants can utilize a prior-registrant’s data and studies (thereby avoiding some or all of the cost, effort, and delay), once the exclusive data-rights period has elapsed. For these products, a later applicant must generally compensate the original registrant if the data is utilized between 10 and 15 years after the original registration,<sup>47</sup> and a later applicant can generally utilize the data without restrictions after 15 years.<sup>48</sup>

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<sup>42</sup> *Id.*

<sup>43</sup> “Use of Standardized Templates to Report Pet Spot-on Incidents: Conclusion of Pilot and Implementation Strategy,” United States Environmental Protection Agency, <https://www.epa.gov/pesticides/use-standardized-templates-report-pet-spot-incidents-conclusion-pilot-and-implementation> (accessed 8/2/2023); “EPA Evaluation of Pet Spot-on Products: Analysis and Plans for Reducing Harmful Effects,” United States Environmental Protection Agency, <https://www.epa.gov/pets/epa-evaluation-pet-spot-products-analysis-and-plans-reducing-harmful-effects> (accessed 8/2/2023); “EPA Evaluation and Regulation of Pet Collar Products,” United States Environmental Protection Agency, <https://www.epa.gov/pets/epa-evaluation-and-regulation-pet-collar-products> (accessed 8/4/2023).

<sup>44</sup> “How to Register a Pesticide – A Guide for Applicants New to the Process,” United States Environmental Protection Agency, <https://www.epa.gov/pesticide-registration/how-register-pesticide-guide-applicants-new-process> (accessed 8/2/2023); “Data Requirements for Pesticide Registration,” United States Environmental Protection Agency, <https://www.epa.gov/pesticide-registration/data-requirements-pesticide-registration> (accessed 8/2/2023).

<sup>45</sup> *Id.*; “Pesticide Registration Manual: Chapter 2 - Registering a Pesticide Product,” United States Environmental Protection Agency, <https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product#newchem> (accessed 8/2/2023).

<sup>46</sup> “Title 7 - Agriculture,” GovInfo, <https://www.govinfo.gov/content/pkg/USCODE-2021-title7/pdf/USCODE-2021-title7-chap6-subchapII-sec136a.pdf> (accessed 8/2/2023), § 136a (c)(1)(F)(i) (“(i) With respect to pesticides containing active ingredients that are initially registered under this subchapter after September 30, 1978, data submitted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration and that pertains solely to such new use, shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticide, except that such permission shall not be required in the case of defensive data.”).

<sup>47</sup> *Id.*, § 136a (c)(1)(F)(iii) (“(iii) Except as otherwise provided in clause (i), with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, to support or maintain in effect an existing registration, or for reregistration, the Administrator may, without the permission of the original data submitter, consider any such item of data in support of an application by any other person (hereinafter in this subparagraph referred to as the ‘applicant’) within the fifteen-year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of delivery to the original data submitter of the offer.”).

<sup>48</sup> *Id.*, at 7 U.S.C. § 136 et seq. (1996), § 136a (c)(1)(F)(iv).



37. In other cases, the FDA regulates the flea and tick treatment.<sup>49</sup> Most of the oral and de-wormer combo products listed above fall under the FDA's purview.<sup>50</sup> A registration and approval process is required for FDA-regulated products, which is somewhat similar in structure to the EPA's registration process. New products require a New Animal Drug Approval ("NADA"), which requires an extensive demonstration of efficacy and safety.<sup>51</sup> Successful NADA registrants are rewarded with 3 to 5 years of exclusivity, in which the FDA will not accept Abbreviated NADA ("ANADA") applications for the same product.<sup>52</sup> Generic animal products (i.e., third-party copies of the original product) may file an ANADA once the exclusivity period has elapsed, utilizing the existing approval of the original product to significantly lessen the burden and time to obtain approval (thereby avoiding some or all of the cost, effort, and delay).<sup>53</sup>

38. Beyond EPA and FDA approval, many new products are also subject to other government-sanctioned intellectual property protections, as is the case in human pharmaceuticals and other technology industries. For example, Frontline and Bayer's Advantage/Advantix products were protected by patents, which expired around 2011 and 2016, respectively.<sup>54</sup> During

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<sup>49</sup> "FDA Regulation of Animal Drugs," United States Food & Drug Administration, <https://www.fda.gov/animal-veterinary/resources-you/fda-regulation-animal-drugs#classifying> (accessed 8/2/2023).

<sup>50</sup> In fact, most of the oral and de-wormer products are in the same class of animal drugs (isoxazoline). See "Fact Sheet for Pet Owners and Veterinarians about Potential Adverse Events Associated with Isoxazoline Flea and Tick Products," United States Food & Drug Administration, <https://www.fda.gov/animal-veterinary/animal-health-literacy/fact-sheet-pet-owners-and-veterinarians-about-potential-adverse-events-associated-isoxazoline-flea> (accessed 8/2/2023).

<sup>51</sup> "FDA Regulation of Animal Drugs," United States Food & Drug Administration, <https://www.fda.gov/animal-veterinary/resources-you/fda-regulation-animal-drugs> (accessed 8/3/2023); "From an Idea to the Marketplace: The Journey of an Animal Drug through the Approval Process," United States Food & Drug Administration, <https://www.fda.gov/animal-veterinary/animal-health-literacy/idea-marketplace-journey-animal-drug-through-approval-process#summary> (accessed 8/2/2023).

<sup>52</sup> "Generic Animal Drugs: Approved or Unapproved?," United States Food & Drug Administration, <https://www.fda.gov/animal-veterinary/unapproved-animal-drugs/generic-animal-drugs-approved-or-unapproved> (accessed 8/2/2023); "Generic Animal Drug and Patent Term Restoration Act (GADPTRA)," United States Food & Drug Administration, <https://www.fda.gov/animal-veterinary/guidance-regulations/generic-animal-drug-and-patent-term-restoration-act-gadptr> (accessed 8/2/2023).

<sup>53</sup> *Id.*

<sup>54</sup> See, e.g., Jeannin, P. "Insecticidal combination to control mammal fleas, in particular fleas on cats and dogs." U.S. Patent 6,096,329, filed May 27, 1997 and issued August 1, 2000. United States Patent and Trademark Office, <https://image-pubs.uspto.gov/dirsearch-public/print/downloadPdf/6096329> (accessed 8/3/2023); Hatton, L. R. et al. "Derivatives of N-phenylpyrazoles." U.S. Patent 5,232,940, filed May 7, 1990 and issued August 3, 1993. United States Patent and Trademark Office, <https://image-pubs.uspto.gov/dirsearch-public/print/downloadPdf/5232940> (accessed 8/3/2023); Sirinyan, K. et al. "Parasiticide formulations suitable for dermal application." U.S. Patent 6,001,858, filed November 27, 1995 and issued December 14, 1999. United States Patent and Trademark Office, <https://image-pubs.uspto.gov/dirsearch-public/print/downloadPdf/6001858> (accessed 8/3/2023); Dorn, H. and Hopkins, T. "Non-systemic control of parasites." U.S. Patent 6,232,328, filed September 8, 1997 and issued May 15, 2001. United States Patent and Trademark Office, <https://image-pubs.uspto.gov/dirsearch-public/print/downloadPdf/6232328> (accessed 8/3/2023).



the pendency of its patent(s), a product is generally protected from competition by generic versions of the product. Once the patent has expired (and when other entry restrictions abate), a product typically sees one or more generic copies enter the marketplace in competition with it. Those generic copies—by copying their reference product and avoiding significant research and development, among other things—are able to save significant costs and, in turn, price substantially lower than the original patented product.

39. Thus, in the animal pharmaceutical space, there are “branded” and “generic” products, just as there are in the human pharmaceutical space. The branded products—like Advantage/Advantix and Frontline—are the original versions that require significant research and development and significant investment in order to be the first to be introduced and receive government approval. For a defined period of time after first introduction, these branded products have government-sanctioned exclusivity. After that defined period of time, generic versions are generally able to copy the branded product and obtain government approval more quickly and at a lower overall cost.

#### 4. Wholesale and Retail Sales Channels

40. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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<sup>55</sup> See, e.g., BAH000050845, p. 7.

41. Retailers obtain their product inventory from wholesalers, meaning the volume and breakdown across sales channels purchased at the wholesale level should generally be consistent with the retail sales channel percentages just discussed. That said, there is no available, comprehensive data showing wholesale sales for all flea and tick treatments. Where possible, I have analyzed the available data for wholesale (Bayer and Frontline) and compared it to the available retail data (those same brands sold at retail).<sup>57</sup> Four main facts stand out as it concerns my analysis that follows.

<sup>56</sup> In general, I endeavor to cite percentages and shares based on doses because that measure is not affected by differences in price. For imidacloprid spot-ons it is less of an issue since Bayer accounts for the majority of the sales across the entire category. In other categories, particularly where there are both significant branded and generic sales, dollar measures will tend to understate the importance of generics, since those sell at significantly lower price points.

46. Both public policy and economic theory concerning branded (i.e., “original,” “pioneer,” and/or “reference”) pharmaceuticals and their generic (i.e., “copy”) counterpart products are well understood and studied.<sup>61</sup> In sum, a successfully-introduced, new branded

<sup>61</sup> Scherer, F. M., “The Pharmaceutical Industry,” in *Handbook of Health Economics*, Volume 1B, edited by Anthony J. Culyer and Joseph P. Newhouse, Elsevier B.V., 2000 (“Scherer (2000)”), pp. 1297-1336 at 1321-1328; Morton, F. S. and Kyle, M. “Markets for Pharmaceutical Products,” in *Handbook of Health Economics*, Volume 2, edited by Mark V. Pauly, Thomas G. McGuire, and Pedro P. Barros, 2011 (“Morton and Kyle (2011)”), pp. 763-823 at 792-795; United States Congressional Budget Office. *Effects of Using Generic Drugs on Medicare’s Prescription Drug Spending*, 2010, pp. 10-12, <https://www.cbo.gov/sites/default/files/111th-congress-2009-2010/reports/09-15-prescriptiondrugs.pdf> (accessed 8/3/2023); United States Government Accountability Office. *Savings from Generic Drug Use*, 2012, <https://www.gao.gov/assets/gao-12-371r.pdf> (accessed 8/3/2023).

product is granted government-sanctioned exclusivity for a *temporary* period of time, allowing it to earn possibly significant profits in recoupment of its initial research and development investments and as a reward for its innovation. *But*, after that temporary period, the government encourages generic copy products to enter the market, providing an important source of competition for the branded product and a low-cost option that is nearly an exact substitute. At bottom, there is a well-understood trade-off: the government agrees to erect significant barriers to entry as a reward for innovation, but those barriers to entry are temporary and give way to competition from identical (but cheaper) products at a well-defined point in time.<sup>62</sup> As two noted economists have summarized:

The extensive use of generics in the US creates a massive and continuing social welfare gain, as these products will be available at close to marginal cost if demand is sustained and the generic markets remain competitive. PBMs' aggressive promotion of generics, as well as other contributing factors such as mandatory substitution laws, means that the branded product typically loses 75 percent or more of its market share very quickly—often in the first year after generic entry. This cliff-like pattern of revenue may be creating strong incentives for innovation by the former monopolist as suggested originally by Arrow (1962).<sup>63</sup>

47. Stated in slightly more detail, the standard economic model of branded versus generic pharmaceutical competition is as follows. First, a company invests in research and development to develop a new drug. As part of this research and development, the company invents and patents the drug, clears an extensive government approval process, and successfully markets and distributes the drug. Second, over the initial sales period the company earns profits as the exclusive seller of that branded drug. Often, those initial profits are significant owing to the novelty of the new branded drug *and* the government-sanctioned exclusivity, achieved by patent and regulatory exclusivity, which protects the branded drug from competition.<sup>64</sup> Third, once the government-sanctioned exclusivity expires, generic products are allowed to enter with

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<sup>62</sup> *Id.*, Scherer (2000), pp. 1321-1322 (“A grand compromise embodied in the Waxman-Hatch Act of 1984...[allowed generic drugs to seek abbreviated, expedited approval.] Thus, they could hit the ground running - perhaps even on the day of patent expiration. As a quid pro quo for the branded drug makers, Congress authorized an extension of the patent protection period to compensate for the delays caused by FDA-required clinical testing regulations. ... Thus, drug developers would be given a longer period of exclusive sales, but would have to face tougher competition once the period of exclusivity ended.”).

<sup>63</sup> Morton and Kyle (2011), p. 795.

<sup>64</sup> Scherer (2000), p. 1317 (“Although altruistic motives undoubtedly enter, profit is the principal lure leading drug makers to invest large sums toward the discovery and development of new drugs. Specifically, company leaders hope to develop products sufficiently important, and sufficiently well insulated from competition, to repay or more than repay their R&D investments.”).

significantly lower prices for essentially the exact same product.<sup>65</sup> In cases where many generic options enter, economic studies have documented generic product prices at discounts of 75% or more versus the pre-generic-entry drug price.<sup>66</sup> Because of these significantly lower prices, generic drugs typically capture the majority of the branded drug's sales over time, with some studies finding almost 100% of consumers substitute to generic drugs in some cases and, on average, generic drugs accounting for upwards of 90% of off-patent drugs sold once they are available.<sup>67</sup> As a prime example, a study from the Congressional Budget Office documented that “within their first full calendar year after patent expiration, [21 branded drugs studied] lost an average of 44 percent of their market (as measured by the quantity of prescriptions sold through pharmacies) to generic drugs,” and one-third of the branded drugs that the CBO studied saw a decline in sales of 65% or more one to three years after their patents expired.<sup>68</sup>

48. Thus, there is a well-known life cycle for pharmaceutical products. An example of the life cycle is summarized in this diagram from the Congressional Budget Office in its discussion of the Hatch-Waxman Act (a key law that promoted generic drug competition).<sup>69</sup>

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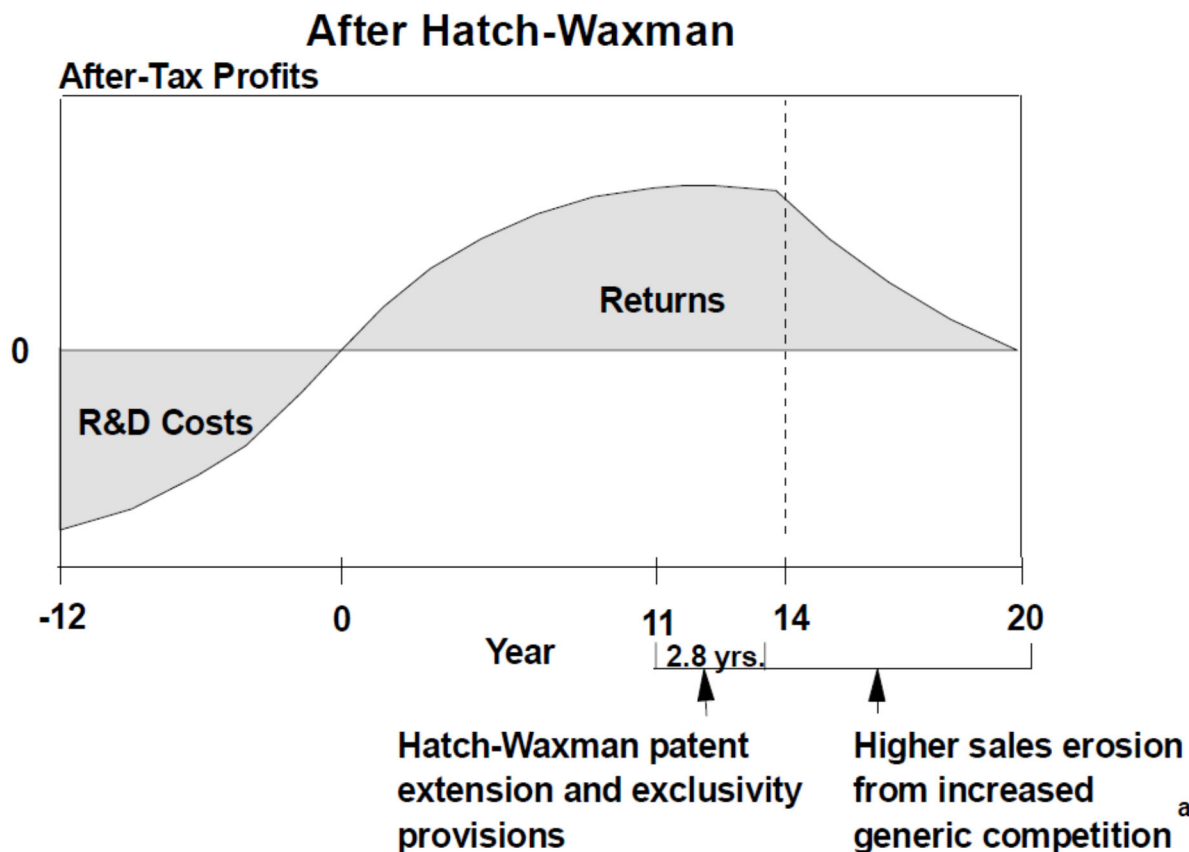
<sup>65</sup> *Id.*, p. 1322.

<sup>66</sup> United States Government Accountability Office. *Savings from Generic Drug Use*, 2012, p. 1 (“On average, the retail price of a generic drug is 75 percent lower than the retail price of a brand-name drug”), <https://www.gao.gov/assets/gao-12-371r.pdf> (accessed 8/3/2023).

<sup>67</sup> Segal, J. B. et al. “Determinants of Generic Drug Substitution in the United States,” *Therapeutic Innovation & Regulatory Science*, Vol. 54, No. 1, 2020, pp. 151-157 at 152 (“In 2016, generic drugs represented 89% of all prescriptions filled in the United States and yet accounted for only 26% of all costs for prescription drugs.”) and Table 2 (showing many generic substitution rates near 100%), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7261594/pdf/nihms-1590328.pdf> (accessed 8/2/2023); United States Congressional Budget Office. *Effects of Using Generic Drugs on Medicare's Prescription Drug Spending*, 2010, at p. vii (“The total number of prescriptions filled under Part D was about 1 billion, of which 65 percent were filled with generic drugs, 5 percent were filled with multiple-source brand-name drugs (brand-name drugs that are also available in generic versions), and 30 percent were filled with single-source brand-name drugs (brand-name drugs for which no chemically equivalent generic versions are available).”) (92.8% = 65%/[65%+5%]) and p. 7 (“Those estimates for Part D of the percentage of prescriptions filled with generic drugs (65 percent) and the percentage of prescriptions written for multiple-source drugs that were filled with the generic option (more than 90 percent) are similar to estimates from other studies of the U.S. market as a whole and of Medicaid. One study found that 69 percent of prescriptions in the United States were filled with generic drugs at the end of 2008. Another study found that 89 percent of prescriptions written for multiple-source drugs were filled with the generic option under the Medicaid program in 2004. Other industry observers have reported that 90 percent or more of prescriptions written for multiple-source drugs were filled with the generic option under plans in the private sector by 2006.”), <https://www.cbo.gov/sites/default/files/111th-congress-2009-2010/reports/09-15-prescriptiondrugs.pdf> (accessed 8/3/2023).

<sup>68</sup> United States Congressional Budget Office. *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, July 1998, p. 28, <https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf> (accessed 8/2/2023).

<sup>69</sup> *Id.*, p. 46. The Hatch-Waxman act is most frequently discussed with regard to human pharmaceuticals, but many concepts from this law and other regulations involving generic drugs in the human pharmaceutical space have an analog in the animal pharmaceutical space. For example, the Hatch-Waxman act implemented the FDA's Abbreviated New Drug Application process. As discussed above, animal drugs registered with the FDA follow a similar process (ANADA) and the EPA has an analogous concept in its registration process.



The last phase of the life-cycle diagram reflects well-understood public policy and economic theory—all branded drugs—including Frontline and Advantage/Advantix—at some point in time ought to hit an “end of life cycle” whereby their sales and profits erode as they give way to sales by their generic competitors.

49. While it is true that human pharmaceuticals and animal pharmaceuticals may vary in some institutional features, the same general economic theory concerning generic competition is applicable in both the human and animal spaces. For example, prescription human pharmaceuticals often have generic substitution laws that require demand to shift from branded to generic drugs,<sup>70</sup> but economic studies have found that generic substitution and competition from generics is an important driver for over-the-counter human pharmaceuticals where generic

<sup>70</sup> For example, the Commonwealth of Massachusetts Title XVI, Chapter 112, Section 12D states that “Except in cases where the practitioner has indicated ‘no substitution’, the pharmacist shall dispense: an interchangeable abuse deterrent product if one exists; or, if none exists, a less expensive, reasonably available, interchangeable drug product as allowed by the most current formulary or supplement thereof.” See “Section 12D,” The 193rd General Court of the Commonwealth of Massachusetts, <https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter112/Section12D> (accessed 8/3/2023).

substitution is not necessarily required by law.<sup>71</sup> And, as I discuss in detail below, Frontline’s history shows a clear, analogous case study of generic substitution for specifically over-the-counter animal pharmaceuticals. Thus, well-accepted economic theory suggests that Bayer’s mature, over-the-counter pharmaceutical—independent of whether it is an animal or human product—should have faced significant, rapid substitution to its generic competitor versions.

50. [REDACTED]

[REDACTED]

### C. Economic Theory of Supply Chains and Exclusive Contracting

51. The allegations in this case concern exclusion of a competitor in the *wholesale* market, but analysis of the end effects to competition and consumers often requires one to shift back and forth between the wholesale and retail markets. As such, it is important to be clear, where possible, as to which market is being analyzed and how they relate to one another. In this

<sup>71</sup> Kohli, E. and Buller, A. “Factors Influencing Consumer Purchasing Patterns of Generic Versus Brand Name Over-the-Counter Drugs,” *Southern Medical Journal*, Vol. 106, No. 2, 2013.

<sup>72</sup> [REDACTED]

<sup>73</sup> See Jeremy Page (Bayer) deposition, 12/7/2022 (“Page deposition”), p. 53: 17-21; Craig Reinert (Bayer) deposition, 2/28/2023 (“Reinert deposition”), p. 21: 1-5.

<sup>74</sup> *Id.*

<sup>75</sup> BAH000250282-7 at 82; BAH000250792-8 at 4 (“Also, to continue the point of overall decline of Frontline...you’ll see that they are losing dollars rapidly”); BAH000101787; Page deposition, p. 73: 4-18; Reinert deposition, p. 54.

subsection, I summarize the key distinctions between the wholesale and retail markets, and I describe the impacts of exclusive dealing by wholesalers on competition, retail markets, and consumers

## 1. Supply Chains: Wholesale Versus Retail Markets

52. Products are supplied from the “upstream” manufacturer (i.e., the company that initially creates the product) to the “downstream” retailer (i.e., the company that sells the product to the ultimate end consumer) via a “supply chain.”<sup>76</sup> Most supply chains consist of multiple separate companies that sell to one another in a “chain” from manufacturer to consumer.<sup>77</sup> For example, Bayer manufactures Advantage/Advantix and sells (a) those products in the wholesale market to pet specialty retailers (e.g., Petco and PetSmart), who then (b) help distribute and market those products, selling to the end consumer (i.e., an individual pet owner).<sup>78</sup> Many of Bayer’s sales in this case follow this two-step supply chain whereby Bayer sells to a large retailer and the retailer sells to the end consumer. As another example, some of Bayer’s sales and many of Frontline’s sales follow a three-step supply chain, whereby (a) the manufacturer (Bayer or Frontline) sells to a distributor, (b) that distributor (e.g., PetIQ) sells to a retailer, and (c) the retailer (e.g., a local pet store) sells to the end consumer. Thus, in this report, discussion of the “wholesale” market refers to the furthest upstream sales from the manufacturer to the retailer or distributor (or direct-to-consumer), and discussion of the “retail” market refers to the furthest downstream sales from the retailer to the end consumer.<sup>79</sup>

53. [REDACTED]

<sup>76</sup> In this case, I try to reserve the term “retailer” to refer to companies that sell to the end consumer, including pet specialty stores, online stores, general merchandisers, and vets.

<sup>77</sup> A supply chain can consist of zero steps or, as is most often the case, two or three successive sales of a product. Some manufacturers are themselves the retailers (i.e., zero steps in the supply chain), manufacturing the product, distributing it, and selling it at retail to consumers. For example, Apple designs and manufactures its computer products, distributes them to its own stores, and sells to consumers in its own stores. But that is not the typical model in the economy generally or in the flea and tick industry.

<sup>78</sup> In this report, I try to reserve the term “customer” and “wholesale customer” for those entities purchasing from the manufacturer. And I try to reserve the term “consumer” for the end individual who purchases the product and then uses it for flea and tick treatment.

<sup>79</sup> It is theoretically possible for a manufacturer to sell direct-to-consumer, in which case the consumer is participating in the wholesale market from an economic standpoint. The economic theory and analysis in this report allow for that theoretical possibility, but as I show, that theoretical possibility is of little practical importance. Whether Tevra could have sold directly to consumers does not diminish the impact of Bayer’s conduct, as I explain further in **Section VI**.



[illegible]

55. Economic analysis of demand tends to move in reverse up the supply chain, starting first with the downstream end-consumer demand. That is, to start, individual consumers demand a flea and tick product (e.g., an individual dog owner going to Petco to purchase a 3-pack of K9 Advantix). As a group, a set of consumers will present a volume of demand to a given retailer, and consumer demand can be aggregated to analyze demand for products at a given store, at a given chain/distributor, or for the retail market as a whole. For example, Petco faces a certain volume of demand for Advantage/Advantix products across its nationwide chain of stores and its online properties, and likewise, Chewy.com faces a certain volume of demand for Advantage/Advantix products on its website.

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<sup>81</sup> See, e.g., "Advantage® II flea treatment for cats and dogs," Elanco, <https://yourpetandyou.elanco.com/us/our-products/advantage-ii> (accessed 8/2/2023) (provides a link to a vet/retailer locator); "Order Online or Find a Retailer," Frontline, <https://frontline.com/where-to-buy?ps-sku=74270> (accessed 8/2/2023).

<sup>82</sup> Tirole, J., *The Theory of Industrial Organization*, 2<sup>nd</sup> ed., The MIT Press, 1988, p. 174.

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56. Importantly, while any one consumer can switch retail purchases between products, the existence of a single isolated individual switching is not the key question in this case. It is true that a given consumer might have, over the course of a decade purchased Frontline, Advantage, Nexgard, and Seresto. But that fact, for that one individual consumer, is not particularly salient. Rather, the switching of many individuals together, thereby causing shifts in the demand from those consumers as a group, is the relevant margin of substitution for understanding retail demand in this case. For example, switching of many individuals from Frontline to generic versions of the product appears to have caused a significant decline in demand (hence, sales) for Frontline. That shift in overall demand by consumers (at the retail level) is the more salient economic fact for this case once one turns upstream to analyze wholesale demand.

57. Retailers endeavor to meet their end consumer demand in many ways, such as through the location of their stores and the services offered. As it concerns this case, retailers control two key variables in order to meet a certain level of demand for flea and tick products: (a) they choose the set of products offered in their stores, and (b) they set the retail prices for which the offered products sell. If retailers select the wrong products or offer an insufficient variety, they will face a lower volume of demand. If retailers face too high of wholesale prices and/or set too high of a mark-up on their products, they will likewise face a lower volume of demand.

58. Retailers' efforts to meet their own end-consumer demand creates upstream demand in the wholesale market. That is, retailers must procure products from manufacturers in the wholesale market in order to, in turn, sell them in the retail market. Unlike individual consumers, most retailers purchase from multiple manufacturers at once in order to offer a variety of products. For example, Petco presently sells at retail (and, thus, buys at wholesale) products from Bayer, Frontline, and many others simultaneously.<sup>84</sup> And, more specifically as an example, Petco offers both Frontline and generic fipronil spot-ons, like PetArmor.<sup>85</sup> Product switching by retailers in the wholesale market tends to be more marginal and continuous in nature than the binary switching observed for any one individual consumer. For example, Petco

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<sup>84</sup> "Dog Flea & Tick," Petco, <https://www.petco.com/shop/en/petcostore/category/dog/dog-and-puppy-flea-and-tick> (accessed 8/2/2023).

<sup>85</sup> *Id.*

might purchase 10% fewer Frontline products and 10% more PetArmor products in a given year, rather than forgo purchases of Frontline or PetArmor entirely. Like retail, analysis of wholesale demand can be done individually (e.g., one large wholesale customer like Petco or PetSmart) or in aggregate (e.g., all wholesale buyers of one manufacturer).

## 2. Exclusive Contracting in the Wholesale Market

59. As I noted above, retailers choose the set of products they supply and their retail prices to drive demand. As it concerns this case, it is typical for retailers to purchase at wholesale and then offer to consumers *both* the branded and generic versions of a particular product. Examples abound outside of the Bayer-dominated products, including Frontline and its generic copies,<sup>86</sup> digestive additives,<sup>87</sup> pet toothpaste,<sup>88</sup> and more. Retailers demand a variety of products from a variety of manufacturers in the wholesale market, thereby achieving their end goal of offering a variety of products to consumers in the retail market, and sufficient high- and low-priced options to attract consumers.

60. However, in certain circumstances, a manufacturer can induce a retailer to circumvent its typical practice and sign an exclusive contract to exclude a manufacturer's competitors. Branded and generic drugs—in competition with one another—present one particular case in which the manufacturer can cause the retailer to limit its products carried. That is, a branded manufacturer can ask a retailer to only offer its product, limiting the product variety and price selection that the retailer typically offers. While this might hurt the retailer due to a reduction in the retailer's overall demand, it benefits the exclusive branded manufacturer by better preserving the branded manufacturer's sales and limiting the competition the branded manufacturer faces at the retail level from generics (e.g., side-by-side price comparisons by consumers). To compensate the retailer for its potential reduction in overall demand (due to the retailer's prospective consumers facing the lesser variety and price selection), the exclusive branded manufacturer can offer a moderate discount at the wholesale level to the retailer. Thus, the branded manufacturer preserves its market position via the exclusive contract, and some of the extra profits it earns under this contract are transferred to the retailer via an exclusivity

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<sup>86</sup> See, e.g., *id.*

<sup>87</sup> See, e.g., "Digestive Health & Probiotics for Dogs," Chewy, <https://www.chewy.com/b/digestive-health-probiotics-1565> (accessed 8/2/2023) (Purina, a branded product, is sold alongside Chewy's private label Vibeful).

<sup>88</sup> See, e.g., Amazon, <https://www.amazon.com/s?k=dog+enzyme+toothpaste&i=pets> (accessed 8/2/2023).

discount in order for the retailer to go along with a scheme that runs contrary to its typical practices.

61. Importantly, while the exclusive contract thus works to the benefit of both the exclusive branded manufacturer and the retailer, it is a harm to end consumers. The result of excluding some products—in this case, the cheaper generic products—causes three effects: (a) lower overall sales quantities, (b) fewer options for consumers, and (c) higher average prices paid by consumers. For example, if retailers offered both the branded and generic versions side-by-side, existing consumers would receive a primary, significant benefit as they face greater choice and can “trade-down” if they choose. Consumers that opt for the cheaper generic make use of that greater variety and receive a direct, immediate benefit from lower prices. Further, those same lower prices can drive additional incremental sales that otherwise might not have occurred, benefitting additional consumers. And, at the same time, the in-store competition of the branded and generic versions has the benefit of driving additional comparative price competition—when versions are displayed side-by-side, it can drive further price reductions. Thus, the benefits are to the clear benefit of end retail consumers, even if there exists a private upstream incentive for the branded manufacturer and retailer to contract exclusively.

62. [REDACTED]

<sup>89</sup> BAH000004613-24 at 22 and 24.

<sup>90</sup> *Id.*

<sup>91</sup> BAH000010171.

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63. To be clear, not all exclusive contracts between a supplier and downstream customer are anticompetitive, both in economics generally and as it concerns generic pharmaceuticals. It is possible for an exclusive contract to enable investment,<sup>93</sup> and in some settings competition among suppliers for an exclusive contract can lead to efficiency gains.<sup>94</sup> On net, there may be benefits to competition and end consumers from the use of exclusive contracts in particular settings. But in other cases—this one included—the net effect is that exclusive contracts exclude competitors, limit competition, and harm consumers. The general economic theory shows that the question of whether the exclusive contract is pro- or anticompetitive depends on many things, including the manufacturer's objectives, the common practices of suppliers and customers, and the net impact to competition and consumers versus the alternative world in which the exclusive contract does not exist.

#### IV. Relevant Markets

64. In antitrust cases, defining a relevant antitrust market is typically an important first step—it pinpoints the “what” and “where” of the case, and it provides a frame to analyze the key allegations, such as the existence of monopoly power, the degree of foreclosure, and the extent of harm to various parties. In this section, I discuss the relevant market for this case: sales of imidacloprid spot-on flea and tick treatments by manufacturers to wholesale customers in the United States. I explain the economic framework and economic evidence that supports this as the properly defined relevant market for this case, and I discuss why other more broadly defined so-called markets are not appropriate and do not fit the economic evidence of this case.

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<sup>92</sup> BAH000011099-104 at 100-104; BAH000066641-4 at 2; BAH000024718-9 at 8; BAH000010156-77.

<sup>93</sup> DeGraba, P. et al., “Conditional Pricing Practices – A Short Primer,” 9/2017, § II.A, [https://www.ftc.gov/system/files/documents/reports/conditional-pricing-practices-short-primer/conditional\\_pricing\\_practices\\_-\\_a\\_short\\_primer\\_-\\_sept\\_2017.pdf](https://www.ftc.gov/system/files/documents/reports/conditional-pricing-practices-short-primer/conditional_pricing_practices_-_a_short_primer_-_sept_2017.pdf) (accessed 8/2/2023).

<sup>94</sup> Calzolari, G. and Denicolò, V., “Competition with Exclusive Contracts and Market-Share Discounts,” *American Economic Review*, Vol. 103, No. 6, 2013, pp. 2384-2411.

## A. Framework for Antitrust Relevant Market Definition

65. A relevant antitrust market is a set of products (and/or services) within a specified geographic area “within which significant substitution in consumption or production occurs.”<sup>95</sup> That is, a relevant market is defined by two dimensions: (a) a product dimension and (b) a geographic dimension.<sup>96</sup> The boundaries of the relevant market along either dimension are typically determined by the degree of economic substitution.<sup>97</sup> A relevant antitrust market is one that *includes* the products (and/or geographic areas) that are *sufficiently* close substitutes such that they have a meaningful impact on the conduct of a firm supplying a product included in the relevant antitrust market. Equivalently, a relevant market *excludes* the products that are *insufficiently* close substitutes such that they do not have meaningful impact on the conduct of a firm supplying a product included in the relevant antitrust market.

66. There are many common examples of sufficient and insufficient substitution that can illustrate the boundaries of a relevant market. For example, in the product dimension, white cars and gray cars are likely highly substitutable for most consumers and are very likely in the same relevant product market. However, cars and motorcycles are likely much less substitutable for most consumers and are likely in different relevant product markets.<sup>98</sup> As another example, in the geographic dimension, two hospitals in the same small town may be substitutable for one another and are likely in the same relevant geographic market. However, two hospitals on different coasts from one another (e.g., Los Angeles and New York) are likely not substitutable and are likely in different relevant geographic markets.

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<sup>95</sup> Areeda, P. E. and Hovenkamp, H., *Antitrust Law: An Analysis of Antitrust Principles and Their Application*, 5<sup>th</sup> ed., Wolters Kluwer, 2023 (“Areeda and Hovenkamp”), ¶530a.

<sup>96</sup> In connection with the merger review process undertaken by the United States Department of Justice and the Federal Trade Commission, these agencies have jointly issued guidelines to be used to assess the competitive effects of mergers. These guidelines discuss relevant market definition and are frequently cited by courts, policy makers, and economists, among others. “Horizontal Merger Guidelines,” United States Department of Justice and The Federal Trade Commission, August 19, 2010, <https://www.justice.gov/atr/horizontal-merger-guidelines-08192010> (accessed 8/2/2023) (“Horizontal Merger Guidelines”), §§ 4.1-4.2.

<sup>97</sup> Horizontal Merger Guidelines, § 4 (“Market definition focuses solely on demand substitution factors, i.e., on customers’ ability and willingness to substitute away from one product to another in response to a price increase or a corresponding non-price change such as a reduction in product quality or service. The responsive actions of suppliers are also important in competitive analysis. They are considered in these Guidelines in the sections addressing the identification of market participants, the measurement of market shares, the analysis of competitive effects, and entry.”); Carlton, D. and Perloff, J., *Modern Industrial Organization*, 4<sup>th</sup> ed., Pearson, 2005 (“Carlton and Perloff”), p. 646 (“a market should include all those products that are close demand or supply substitutes”).

<sup>98</sup> Horizontal Merger Guidelines, § 4.1.1 (Example 7).

67. The “hypothetical monopolist test” (“HMT”) is often used to quantify the degree of sufficient (or insufficient) substitution and test the boundaries of the relevant market.<sup>99</sup> This test involves a thought experiment in which a hypothetical monopolist of a candidate relevant market (e.g., a candidate market of only white and gray cars) raises the price of goods in that market by a small but significant amount (a “SSNIP”).<sup>100</sup> If substitution by consumers out of that candidate market (e.g., to black cars) would render that hypothetical price increase unprofitable, then the candidate product market is too small and the process is repeated with a larger market (e.g., a market that includes white, gray, and black cars). Once the market is large enough and substitution out of the candidate market is substantially reduced such that the hypothetical price increase would be profitable (e.g., a market of all colored cars but not including motorcycles), the test stops and the relevant market is confirmed. In other words, the HMT begins with a small candidate market, iteratively adding one marginal substitute at a time, stopping when the next marginal product is no longer sufficient to prevent a price increase. I use this framework below to demonstrate that imidacloprid spot-on flea and tick treatments in the U.S. is the relevant antitrust market in this case.

68. I understand that courts have accepted the HMT as a reliable method for determining relevant markets in litigation.<sup>101</sup> Furthermore, the HMT does not have to—nor should it necessarily—encompass every possible or theoretical substitute product.<sup>102</sup> For example, to test a relevant market for cars, the HMT need not consider literally every motorized, wheeled vehicle from motorcycles, to cars, to busses. Rather, the HMT can begin with a small market (e.g., cars only) and work iteratively to the point in which the marginal product is identified, drawing a line between what is and is not sufficient to be relevant for the case. In this

<sup>99</sup> Horizontal Merger Guidelines, § 4.1.1.

<sup>100</sup> *Id.* (“Specifically, the test requires that a hypothetical profit-maximizing firm, not subject to price regulation, that was the only present and future seller of those products (‘hypothetical monopolist’) likely would impose at least a small but significant and non-transitory increase in price (‘SSNIP’) on at least one product in the market[.]”).

<sup>101</sup> See, e.g., *Federal Trade Commission and Commonwealth of Pennsylvania v. Penn State Hershey Medical Center and Pinnacle Health System*, No. 16-2365 (3rd Cir. 2016), § IV.A.1.b; *United States of America, et al. v. Aetna Inc, et al.*, No. 16-1494 (D.C. Cir. 2017), pp. 21-22.

<sup>102</sup> Horizontal Merger Guidelines, p. 8.

way, the HMT and the resulting relevant market definition specifically “helps specify the line of commerce and section of the country in which the *competitive concern arises*.”<sup>103</sup>

## B. The United States is the Relevant Geographic Market

69. The relevant geographic market encompasses the United States and the manufacturers and wholesale customers that transact within it. Manufacturers that supply flea and tick products are subject to stringent U.S. regulations, such as EPA and FDA approval, as discussed previously. Manufacturers also have U.S.-based operational and infrastructure requirements, such as networks of sales and distribution employees.<sup>104</sup> Those regulations and operational needs prevent non-U.S. manufacturers from selling in the United States, just as analogous non-U.S. regulations and operational needs prevent U.S. manufacturers from selling abroad. Likewise, wholesale customers face essentially those same regulatory and operational impediments themselves buying in/out of the United States. U.S. retailers and distributors could not source their wholesale purchases from non-U.S. manufacturers, nor could those retailers and distributors move their own operations abroad and still effectively serve their U.S. consumers.<sup>105</sup>

70. The HMT is satisfied for a candidate market of the United States but excluding other countries. A hypothetical monopolist of all U.S. manufacturers could successfully raise wholesale prices by a SSNIP for flea and tick products, as both U.S. retailers and distributors and U.S. consumers would have no choice but to accede to such a price increase. Neither wholesale customers (retailers and distributors) nor consumers would forgo supply of US flea and tick products, nor could they obtain the products from abroad in any effective way. Because customers would accede to the SSNIP under this hypothetical, the HMT confirms the relevant geographic market is the United States and not larger.

<sup>103</sup> Horizontal Merger Guidelines, p. 7 (emphasis added).

<sup>104</sup> [REDACTED]

<sup>105</sup> For example, Petco and PetSmart could not move their many physical stores outside of the U.S. and still operate a viable U.S. retail business.



### **C. Imidacloprid Spot-On Products Sold to Wholesale Customers are the Relevant Product Market**

71. The relevant products in this case involve sales between the manufacturer—Bayer and Tevra—and wholesale customers. The products sold to these wholesale customers are appropriately limited to only imidacloprid spot-on products—including Bayer’s Advantage/Advantix products and their generic equivalents, like Tevra’s Activate/Avantect.

#### **1. Bayer and Tevra Compete in the Wholesale Market**

72. Tevra and Bayer—the two parties to this case—are drug manufacturers that participate in the *wholesale* market. That is, they are companies that serve as the effective starting point for the supply chain that ultimately routes and delivers products from factories to end consumers. Tevra and Bayer generally sell their products in bulk quantities to other companies (retailers or distributors), and those other companies then re-sell those products in small quantities to individual consumers.<sup>106</sup> Multi-step supply chains are a well-understood concept in economics, and it is common for economic analysis to specify a particular point in the supply chain as the relevant market.<sup>107</sup>

73. The fact that the wholesale market is the relevant market for this case does not mean wholesale and retail markets are unrelated. As I explained previously, demand from consumers at the retail level helps dictate demand by retailers and distributors purchasing at the wholesale level, and supply restrictions at the wholesale level will dictate what products (and prices) are available to consumers at the retail level. In this case, as it concerns relevant market definition, analysis is properly done by considering the impact of Bayer’s alleged conduct in the wholesale market, as that is the level of the supply chain in which Bayer and Tevra compete and in which Bayer’s conduct harmed Tevra and other generic imidacloprid spot-on companies.

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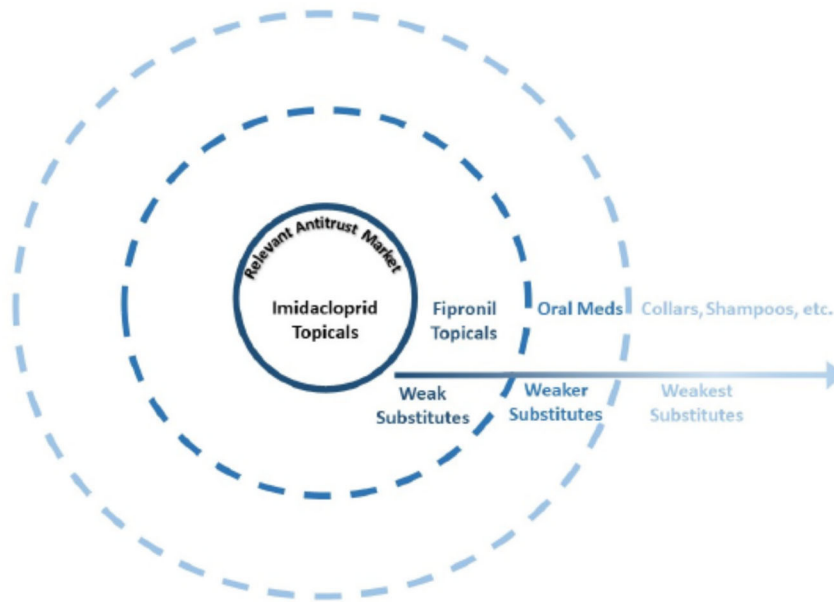
<sup>106</sup> On some occasions, there are one or more distributor middle-men in between the manufacturers like Tevra and Bayer and the individual consumers. Those distributors buy from the manufacturer in large quantities and re-sell in smaller quantities to retailers. Those retailers, in turn, re-sell the purchased product to individual consumers. For flea and tick treatments, the supply chain typically has two (manufacturer to retailer to consumer) or three links (manufacturer to distributor to retailer to consumer).

<sup>107</sup> “Vertical Merger Guidelines,” United States Department of Justice and The Federal Trade Commission, June 30, 2020, [https://www.ftc.gov/system/files/documents/reports/us-department-justice-federal-trade-commission-vertical-merger-guidelines/vertical\\_merger\\_guidelines\\_6-30-20.pdf](https://www.ftc.gov/system/files/documents/reports/us-department-justice-federal-trade-commission-vertical-merger-guidelines/vertical_merger_guidelines_6-30-20.pdf) (accessed 8/2/2023), pp. 1 (“vertical mergers (those that combine firms or assets at different stages of the same supply chain)”) and 3 (describing an example in which the relevant market is wholesale “competition between manufacturers of cleaning products”).

## 2. Imidacloprid Spot-On Products are Appropriately Defined as their Own Relevant Product Market

74. Within the U.S. wholesale market for flea and tick treatments, there is a dispute between the parties as to the boundaries of the relevant product market for this case. Tevra alleges that imidacloprid spot-on products—including Bayer’s Advantage/Advantix and its generic copies, like Tevra’s Activate/Avantect—are the only products within the relevant product market.<sup>108</sup> Bayer has contended that the relevant market is much larger, including other flea and tick treatments, namely Frontline and fipronil spot-ons more generally.<sup>109</sup> Based on my analysis below, it is my expert opinion that Tevra’s alleged relevant product market—only imidacloprid spot-ons—is the appropriately defined relevant market for this case.

75. In its complaint, Tevra proposes the candidate market of only imidacloprid spot-ons and alleges an HMT to test its proposed candidate market. Tevra’s proposed market and HMT are summarized in this diagram from its complaint:<sup>110</sup>



**Diagram 2 - Application of the HMT to the Relevant Antitrust Market for Imidacloprid Topicals**

<sup>108</sup> SAC, ¶ 18.

<sup>109</sup> Order Denying Defendant's 12(b)(6) Motion To Dismiss Second Amended Complaint filed January 6, 2022, p. 9 (“Unsurprisingly, Bayer takes issue with the adequacy of this pleading, arguing that Tevra’s relevant market is implausibly narrow and excludes the most direct and obvious competitor—Frontline, a fipronil topical.”).

<sup>110</sup> SAC, ¶ 37.

Tevra alleges that substitution from imidacloprid spot-ons to other products is relatively minimal, such that a hypothetical monopolist of only imidacloprid spot-ons would be able to raise price by a SSNIP without losing too many sales to competitor products (e.g., fipronil spot-ons) and thereby rendering that price increase unprofitable.<sup>111</sup> As discussed above, Tevra's alleged framework is consistent with common antitrust analyses, including those undertaken by federal antitrust agencies.

76. I have analyzed data to empirically test Tevra's alleged HMT and confirmed Tevra's alleged relevant market—only imidacloprid spot-ons—is the correct one for this case. From 2010 to 2016, Bayer was an actual monopolist (and, thus, also the hypothetical monopolist) in Tevra's alleged candidate market—it was the only seller of imidacloprid spot-ons during that period of time due to its government-sanctioned exclusivity. And during that period of time, Bayer was able to raise its prices by more than a SSNIP, both in absolute and relative terms, earn larger profits, *and* sell more quantity. Thus, over at least a seven-year period, Bayer's own conduct satisfies the HMT exactly—Bayer, as the monopolist of the candidate market, was able to successfully institute a SSNIP. Moreover, over that same history, the products that Bayer contends belong within the relevant market became increasingly available and cheaper. And yet, those other products did not attract significant substitution from imidacloprid spot-ons, and they did not defeat Bayer's SSNIP. The inability of those other products to discipline Bayer's own pricing and the lack of substitution away from Bayer's products demonstrates that those other products are insufficient substitutes and should be excluded from the relevant market.

**a. Bayer's Price Increase from 2010 to 2016: A Natural Experiment that Proves the Hypothetical Monopolist Test**

77. This case is somewhat unique in that the history of flea and tick products provides a “natural experiment” that almost exactly replicates the test outlined in the HMT analytical framework.<sup>112</sup> To explain this in more detail, consider the set of products (and suppliers of those

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<sup>111</sup> SAC, ¶ 34.

<sup>112</sup> Wong, P. and Ramanarayanan, S., “Reduced-Form versus Structural Econometric Methods in Market Definition: Lessons from Aetna-Humana,” Antitrust Health Care Chronicle, June 2017, [https://www.nera.com/content/dam/nera/publications/2017/ABA\\_Health\\_Care\\_Chronicle-Final-6-9-17%20\(2\).pdf](https://www.nera.com/content/dam/nera/publications/2017/ABA_Health_Care_Chronicle-Final-6-9-17%20(2).pdf) (accessed 8/2/2023), p. 20 (“Reduced-form methods can encompass analyzing a ‘natural experiment’ that has occurred in the past, or examining variation in competitive conditions and outcomes across markets. Based on the patterns in the data and the analysis that is implemented, one can either directly assess whether a candidate market passes the Hypothetical Monopolist Test (e.g., by analysis of a natural experiment), or one can use direct evidence on market outcomes to make inferences about the scope of the relevant market.”).

products) as of about 2010. As summarized in **Exhibit 3A**, these were largely the only flea and tick treatments available to U.S. customers at that time:

- a) Bayer's Advantage/Advantix imidacloprid spot-ons;
- b) Frontline's fipronil spot-ons;
- c) Other chemical spot-ons;
- d) A set of de-wormer combo treatments and other miscellaneous products like shampoos and sprays.

Thus, as of 2010, it is possible to conceive of the candidate market of only imidacloprid spot-ons (i.e., focusing only on that one product) and conceive of a hypothetical monopolist (i.e., focusing on the one firm supplying that one product). At that time, that candidate market was literally a monopoly, since Bayer held EPA exclusivity and patent protection to the state-sanctioned exclusion of other competitors until about 2016. Thus, from that point in time, it is possible to conduct an HMT of the candidate imidacloprid-only market by analyzing Bayer's subsequent conduct and how the set of flea and tick products, more generally, evolved. The key historical changes after 2010 provide direct confirmation of the HMT.

78.

<sup>115</sup> Horizontal Merger Guidelines, § 4.1.2.

81. If fipronil products were close substitutes for Bayer's imidacloprid products—as Bayer contends—the alleged competition from these substantially lower priced generic fipronil products should have appeared to customers (wholesale and retail) as a significant price increase for Bayer in relative terms. That is, economists widely understand that customers react to relative prices and the opportunity cost that alternative products present.<sup>118</sup> If fipronil products are sufficient substitutes for imidacloprid products and fipronil products are suddenly much more attractive (driven by drastic price reductions), it should make imidacloprid products appear suddenly much worse from an economic perspective. Thus, the introduction of such substantially cheaper fipronil products from 2010 to 2016 should have had the same economic effect as if

<sup>118</sup> Buchanan, J. M., "Opportunity Cost," in *The New Palgrave Dictionary of Economics*, Palgrave Macmillan, 2008.

Bayer had instituted a price increase. Over time, even if Bayer's price had remained flat in absolute dollar terms, the growing availability of fipronil generic spot-ons—at prices roughly 14% or more below Bayer—would have created a relative price difference that is tantamount to a price increase far in excess of any common conceptualization of a SSNIP.

82. [REDACTED]

83. Fourth, the economic evidence is not consistent with Bayer's price increases being driven by market factors as opposed to Bayer's own conduct. For example, there was no sudden, unexpected increase in demand for Bayer's spot-on treatments at the time of the price increase. Rather, as shown in **Exhibit 3B**, the demand for imidacloprid spot-ons and spot-ons more generally was relatively flat. Moreover, as shown in **Exhibit 6B**, the price increase for Bayer's Advantage/Advantix was substantially higher than other spot-on products—Bayer's price increase was nearly double that of Frontline by 2016 (and more than 10-fold by 2019). Furthermore, the key economic shock—namely, generic entry—should have reduced rather than increased the demand for Bayer's products. Further still, the data do not show that increases in the cost of the products themselves caused the price increase. Over this time period, Bayer's prices rose relative to other products, including Frontline and generics, and Bayer's profit margins (i.e., its price relative to its costs) increased, as shown in **Exhibit 10** below.

84. Thus, in both absolute and relative terms, Bayer raised its prices considerably, well over the SSNIP asked for under the HMT. This fact, on its own, is sufficient to prove the

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<sup>119</sup> See, *supra*, **Exhibit 3C**.

HMT and Tevra's alleged relevant market of only imidacloprid spot-ons. Bayer was—in the real-world as the literal (and hypothetical) monopolist as of 2010—able to actually implement and sustain a significant increase in price in the alleged relevant market despite newly introduced generic products, drastically lower prices for other products, wider product availability generally, and growing variety and competition in the industry. Bayer's success, and the inability of these other products to successfully discipline Bayer's conduct, shows (a) the candidate market of only imidacloprid spot-ons passes the HMT and is a properly defined relevant market, and (b) those other products—which failed to discipline Bayer—are properly excluded from the relevant market.

**b. Bayer Successfully Retained (and Grew) its Sales Quantities Despite Its Higher Prices**

85. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

87. To be clear, my analysis shows a clear distinction between the history of Bayer's Advantage/Advantix and Frontline. Here is a summary of the key economic facts:

- a) Bayer—the only seller of imidacloprid spot-ons as of 2010 and 2011:
  - i) Raised its prices in absolute by at least 10%, and in relative terms by a similar magnitude, with its difference to the average fipronil spot-on price growing from -7% in 2010-2011 to +4% by 2016 (+11 percentage points), and selling at almost double the price of Seresto and at a significant premium to generic imidacloprid spot-ons as of 2016;
  - ii) Bayer saw no decline in sales—i.e., essentially no substitution toward other products in reaction to its price increase.
- b) Frontline—the only seller of fipronil spot-ons as of 2010:
  - i) Also raised its prices in absolute by almost 6%, and a larger amount in relative terms, with its premium to generic fipronil products growing from zero in 2010 (as the only seller) to 23% by 2016;
  - ii) But Frontline did see a decline in sales of more than 57%—i.e., significant substitution toward other products in reaction to its increase in prices.

88. Although the comparison is clear to the eye simply by looking at the two trends in **Exhibit 7A**, a difference-in-differences regression framework can be used to formally test the comparison between Bayer's Advantage/Advantix and Frontline. This regression technique is widely used throughout economics (and sciences more generally) to demonstrate the statistical significance of a comparison of trends between two groups.<sup>121</sup> In this setting, the difference-in-differences regression looks at the trend over time in Frontline's sales as the baseline ("control") impact that should occur as a branded pharmaceutical product is exposed to increased competition from cheaper, closely substitutable products. As is clear in the chart and as basic economic theory instructs (see chart in-text in Section III.B), the branded product should see an increasing loss of sales as customers shift to those substitutable products. That baseline trend for Frontline can be contrasted with the trend over the same time for Bayer—the difference between the two trends is the "difference-in-differences" for which the regression method is named. Mathematically, this can be specified in the following regression equation:

<sup>121</sup> Abadie, A., "Difference-in-Difference Estimators," in *The New Palgrave Dictionary of Economics*, Palgrave Macmillan, 2008.



$$sales_{it} = \beta_0 + \beta_1 * Frontline + \beta_2 * competition_t + \underbrace{\beta_3 * competition_t * Frontline}_{\text{difference-in-differences}} + \epsilon_{it}$$

where  $i$  and  $t$  represent the company (Bayer or Frontline) and a point in time, respectively, and the dependent variable  $sales_{it}$  measures each company's sales quantity over time. The first two coefficients ( $\beta_0$  and  $\beta_1$ ) allow for the fact that initial sales quantities vary across companies. The third coefficient ( $\beta_2$ ) accounts for the effect of competition, quantified with the measure  $competition_t$ . The last coefficient ( $\beta_3$ ) is the difference-in-differences estimator and captures the differential effect of competition on Frontline relative to its effect on Bayer. Thus, with this regression,  $\beta_2$  quantifies the effect of competition on Bayer,  $\beta_2 + \beta_3$  quantifies the effect of competition on Frontline, and  $\beta_3$  is the incremental difference in effects comparing Bayer and Frontline.

89. **Exhibits 8A to 8C** show the results from a few different specifications of the difference-in-differences regression. Across the different specifications, I vary the unit of measure of sales (normalized quantity, log dose quantity, and dose quantity), the measure of competition (accounting for generic fipronil competition, Seresto and oral competition, and/or generic imidacloprid competition), and the unit of observation (companywide or split by species).<sup>122</sup> As the results show, the regressions confirm two key economic facts:

- a) Bayer's products (Advantage and Advantix) exhibit no statistically significant response to competition from products beyond imidacloprid, including fipronil generics—consistent with the charts that illustrate no loss in sales for Bayer;
- b) Frontline exhibits a statistically and economically significant loss in sales in response to increasing competition from fipronil generics—this loss is significant relative to the initial pre-generic-entry sales and relative to Bayer's own experience.

To be clear, these regressions are a re-confirmation of what is apparent in the charts and in the economic theory—whereas Bayer had monopoly power and its sales were insulated from substitution by various economic barriers, Frontline experienced a significant loss in sales as customers substituted to other products, principally to generic fipronil spot-ons.

<sup>122</sup> The results are also robust to varying the unit of time, as the results are essentially identical when run on quarterly or monthly data rather than annual data.

90. There is significant evidence to show that the differential loss in sales for Frontline quantified by the regressions was indeed caused by customer substitution to other products. First, as I show in **Exhibit 3B**, generic fipronil products attain about half of total fipronil sales by 2016, which is roughly consistent with Frontline's loss in sales to that same point. This is consistent with standard economic theory and is clear evidence of customers substituting (i.e., "trading down") from the branded product, Frontline, to the generic products. Second, Bayer's own ordinary course documents exhibit essentially the same study comparing Bayer and Frontline, noting contemporaneously that Frontline's decline in sales is directly attributable to customer substitution from the branded to the generic product.<sup>123</sup> Third, the main statistic of interest for the HMT is not just whether 90% or 100% of Frontline's lost sales diverted to generic fipronil spot-ons—rather, it is also the fact that Bayer saw no significant loss of sales whatsoever. The two trends for branded products compared to one another show that (a) the cross-elasticity of demand between Bayer's Advantage/Advantix and other products was essentially zero up to 2016, whereas (b) the cross-elasticity of demand between Frontline and its generic fipronil copies was very large.

91. Thus, Bayer's actual, successful increase in price and its lack of lost sales—particularly compared to the significant loss fared by Frontline—confirms the HMT passes for a relevant product market of only imidacloprid spot-ons. The history of sales for Bayer's Advantage/Advantix shows a dedicated, insulated contingent of demand that was unwilling to substitute to other products—namely, fipronil spot-ons—despite Bayer's increase in prices. Because of this lack of substitution, the HMT is satisfied and those other non-imidacloprid products should be excluded from the relevant market.

**c. Bayer's Own Evidence Also Confirms the Relevant Product Market Definition**

92. Bayer's own ordinary course documents and deposition testimony confirm the results of the above HMT and show that the appropriately defined relevant product market is limited to only imidacloprid spot-ons. This evidence shows Bayer's contemporaneous recognition that other products (e.g., fipronil spot-ons) are imperfect, insufficient substitutes for imidacloprid spot-ons.

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<sup>123</sup> [REDACTED]

<sup>128</sup> Horizontal Merger Guidelines, § 4.1.1 at Example 6 (explaining a hypothetical in which Product C has a 50% diversion ratio and Product B has a 33% diversion ratio, and concluding “Product C is a closer substitute for Product A than is Product B. Thus, Product C will normally be included in the relevant market”). It follows that, if the diversion ratio from Advantage/Advantix to generic imidacloprid products is nearly 100%, then the diversion ratio to all other products is near zero. Thus, the diversion ratio for the products within the relevant market (imidacloprid spot-ons) is far larger than the diversion ratio (cumulatively or individually) to other products outside the relevant market, in keeping with the example discussing Product C.

[illegible]

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[illegible]

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[REDACTED]  
 [REDACTED]  
 [REDACTED]  
 [REDACTED]  
 [REDACTED]  
 [REDACTED]  
 [REDACTED] c

<sup>129</sup> See Exhibits 11A to 11Q.

<sup>130</sup> BAH000257075 at pp. 13-16

<sup>131</sup> Thad Howell (Bayer) deposition, 2/8/2023, p. 47: 7-13.

## V. Monopoly Power

97. It is my expert opinion as a matter of economics that Bayer held monopoly power until at least 2016. In this section, I discuss the economic evidence that demonstrates Bayer's monopoly power. In the next section, I discuss steps Bayer undertook after 2016 in a successful effort to maintain its monopoly power longer than would have occurred otherwise.

### A. Framework for Assessing Monopoly Power

98. Economists define "market power" as the ability to set prices above the marginal cost of production. Economists understand that most firms hold some degree of market power and so modern inquiries of market power usually involve an assessment of the degree to which prices exceed the competitive levels of a particular setting.<sup>133</sup> Thus, antitrust matters typically concern firms that have a significant degree of market power (i.e., prices are significantly above competitive levels) and, when market power is very substantial, "monopoly power."<sup>134</sup> As Areeda and Hovenkamp's treatise notes: "[T]he substantial market power that concerns antitrust law arises when the defendant (1) can profitably set prices well above its costs and (2) enjoys some protection against rivals' entry or expansion that would erode such supracompetitive prices and profits."<sup>135</sup> Significant market power and/or monopoly power ultimately harms society because it reduces output and transfers rents that would otherwise be kept by customers and consumers.<sup>136</sup>

99. In keeping with the economic definitions, economists have two well-accepted methods for assessing whether a firm has gained or maintained significant market power (or monopoly power) in a relevant market. First, one can potentially infer a likelihood of market power indirectly through (a) high market shares in an appropriately defined relevant antitrust

<sup>132</sup> Bauer deposition, p. 228: 4-9.

<sup>133</sup> Areeda and Hovenkamp, ¶501; Carlton and Perloff, pp. 642-43.

<sup>134</sup> *Id.*

<sup>135</sup> *Id.*

<sup>136</sup> Carlton and Perloff, pp. 89-93.

market and (b) the existence of barriers to entry that prevent (or slow) competitors from significantly diminishing that market share.<sup>137</sup> Second, one can identify market power directly through (a) direct evidence of the key indicators of market power (supracompetitive prices and profits and/or restricted supply) and/or (b) anticompetitive market outcomes for customers and consumers, such as reduced product variety and harm to consumer welfare.<sup>138</sup> When using the indirect method, monopoly power is often considered possible when there are market shares at or above 50%,<sup>139</sup> and there are significant long-run barriers to entry that prevent competitors from entering or expanding, helping to preserve an incumbent over a period of time.<sup>140</sup> When using direct methods, economists often look at prices for the alleged monopolist relative to a variety of benchmarks, including other substitute products, costs of production, and changes over time.<sup>141</sup> Other direct methods can include analysis of reduced output and/or product variety, or the exclusion of competitors.<sup>142</sup>

100. The two approaches may agree or disagree in any one case, and a determination of significant market or monopoly power concerns an overall assessment of the economic evidence. In some cases, the overall assessment is clear, as the indirect method of shares and market structure may be consistent with an expectation of significant market power, and the direct method may be used to confirm that expectation. In other cases, one or both methods may be used to rule out the existence of significant market power—e.g., a trivial market share of 1% to 2% is likely sufficient to rule out any concern about market power and no assessment of direct evidence of market power is likely to be needed. This case follows the former pattern—the

<sup>137</sup> Carlton and Perloff, p. 77; Horizontal Merger Guidelines, pp. 16-17 and 27-28.

<sup>138</sup> Horizontal Merger Guidelines, pp. 11-12; Areeda and Hovenkamp, Chapter 5.

<sup>139</sup> Carlton and Perloff, p. 644; “Competition And Monopoly: Single-Firm Conduct Under Section 2 Of The Sherman Act: Chapter 2,” United States Department of Justice, <https://www.justice.gov/atr/competition-and-monopoly-single-firm-conduct-under-section-2-sherman-act-chapter-2> (accessed 8/3/2023); “Monopolization Defined,” Federal Trade Commission, <https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/single-firm-conduct/monopolization-defined> (accessed 8/3/2023).

<sup>140</sup> Carlton and Perloff, p. 77 (describing a patent as a “good example” of a “long-run barrier to entry”); Horizontal Merger Guidelines, p. 28 (“prospect of entry into the relevant market will alleviate concerns about adverse competitive effects only if such entry will deter or counteract any competitive effects”).

<sup>141</sup> “Competition And Monopoly: Single-Firm Conduct Under Section 2 of The Sherman Act: Chapter 2,” United States Department of Justice, <https://www.justice.gov/atr/competition-and-monopoly-single-firm-conduct-under-section-2-sherman-act-chapter-2> (accessed 8/3/2023); “Monopolization Defined,” Federal Trade Commission, <https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/single-firm-conduct/monopolization-defined> (accessed 8/3/2023).

<sup>142</sup> *Id.*

indirect and direct methods of assessing market power are consistent with one another and show Bayer held monopoly power.

## **B. Market Share and Barriers to Entry**

101. In light of the extensive discussion of the relevant antitrust market above, the calculation of market shares is straightforward. **Exhibit 9** shows my calculations of market shares for the relevant market of imidacloprid spot-ons sold in the U.S. at the wholesale level.<sup>143</sup> Up to 2015, Bayer accounted for 100% market share given it held EPA exclusivity and other protections and competing products had not yet entered. In 2016, the first year of generic competitor entry, Bayer still held 95% market share, and by 2019, Bayer still held 87% market share. This high level of market share is consistent with common indicators of monopoly power. And while this is a high market share in its own right, it is also notable compared to the experience of Frontline. Whereas Bayer continues to have market share on a level consistent with monopoly power, Frontline accounted for only about half of fipronil spot-on sales in 2016 (six years after generic entry) as shown in **Exhibit 3B**.

102. Assessment of high barriers to entry for the relevant market is also straightforward given the discussion above. There are clear barriers to entry, as I discuss in Sections III.A.3 and IV.B, including large regulatory barriers and intellectual property protections. In the relative market for imidacloprid spot-ons, those barriers—namely Bayer’s EPA exclusivity and patents—were essentially absolute, as no other product successfully entered until 2016. Even after that point, there were significant barriers to entry and expansion—including Bayer’s effort to erect an additional, artificial barrier via its anticompetitive contracts, as discussed below—as is shown by generic competitors’ collective inability to enter and expand thus far. Again, the comparison to Frontline and fipronil is illuminative—whereas competitors have clearly entered and expanded in fipronil, they have not done the same in imidacloprid. That contrast demonstrates the ongoing existence of significant barriers to entry.

103. Thus, the main two criteria are met, suggesting a likelihood that Bayer held and maintained monopoly power in the relevant market for imidacloprid spot-ons. Bayer has had

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<sup>143</sup> My baseline calculations assess market shares based on monthly doses sold (a standardized unit of measure). As also noted above, I prefer this measure (rather than sales dollars) where possible, as it is not affected by differences in pricing across products, and it lets one compare different pet species and/or types of products (e.g., Advantix versus Seresto) as needed. Analysis of sales dollars, rather than doses, will tend to understate the size of generic products relative to branded products, and my use of dose quantities works conservatively in Bayer’s favor in assessing monopoly power.

over 85% market share for nearly a decade, did not face entry from a competitor until 2016, and successfully maintained its high market share past the point in which other similarly situated firms (namely, Frontline) saw a decline in their own sales and market position.

### **C. Prices and Profit Margins**

104. The direct evidence of Bayer's monopoly power is equally straightforward in light of the above discussion. As shown in **Exhibits 5A and 6A**, Bayer's own data shows that it successfully raised prices until 2016, both in absolute compared to what it was charging at the start of the observable period and in relative terms compared to other products available in the industry. And, as shown in **Exhibit 7A**, Bayer instituted these price increases without losing sales. Combined, these charts and the detailed analysis above clearly show Bayer's ability to price above competitive levels, as is specified in the definition of monopoly power.

105. Comparing Bayer's profit margins and prices for Advantage/Advantix to generic competitors' profit margins and prices, like those from Tevra, also helps confirm that Bayer maintains a supracompetitive price. **Exhibits 3C and 6B** show that Advantage/Advantix sell for far more than generic imidacloprid versions, like Tevra's Activate/Avantect. Similarly, **Exhibit 10** shows the profit margins for Bayer (both gross and operating margins) are significantly above those of Tevra. These comparisons show that Bayer charges significantly more than other comparable products, and the gap between Bayer and other products has grown. Thus, in addition to the fact that Bayer increased its own prices, a comparison of prices and profit margins across the industry shows clear direct economic evidence that Bayer charges prices consistent with monopoly power.

106. It is true that pharmaceutical prices often show an evolution over time that is not necessarily found in other industries and the true definition of the "competitive" price can be a contentious question. Here, it is clear from Bayer's own data that Bayer set a price well above its cost of production as early as 2010 when it faced no competition from closely substitutable products in the eyes of customers. It is true that Bayer faced some modicum of competition from other flea and tick treatments, generally, but that modicum of competition was (a) insufficient to discipline Bayer's price setting (hence, leaving those products out of the relevant market) and (b) insufficient for Bayer's 2010 price to be considered a "competitive" benchmark. Rather, it is my opinion as a matter of economics that Bayer's 2010 pricing was supracompetitive and it raised its



price above that point—thus, showing a monopoly price consistent with what would be economically rational for Bayer to select given its lack of significant competition.

107. Since 2016 Bayer’s price has stayed relatively constant despite the introduction of much lower generic product prices that are much closer to the cost of production and better thought of as the “competitive” benchmark price. That persistent price gap between Bayer and its generic copies, like Tevra’s Activate/Avantect, is further evidence that Bayer originally set (before 2016) a price at monopoly levels and has maintained the monopoly price level since. It is true that branded pharmaceuticals often make such a choice, maintaining their same pricing (or nearly so) over time despite generic entry.<sup>144</sup> Thus, Bayer’s decision to maintain monopoly pricing is something that is also observed in other instances and is not in itself the anticompetitive issue. Rather, as I discuss below, Bayer’s decision to maintain its monopoly price *and* its efforts to prevent competition and customer switching in the face of that monopoly price is the anticompetitive issue.

108. Thus, in confirmation of the indirect evidence of high market share and barriers to entry, there is direct evidence through Bayer’s prices and profit margins that Bayer held (and holds) monopoly power. Bayer set a supracompetitive price for its Advantage/Advantix products as of 2010 and 2011, raised that price through 2016, and has continued to charge nearly that same price (or more) over time despite increasing availability of cheaper products.

#### **D. Bayer’s Exclusion of Competition and Bayer’s Monopoly Power Over Time**

109. As will be discussed in the next section, Bayer’s contracts had the purpose and effect of excluding all lower priced competitors of a particular type. This too, is direct evidence of monopoly power where the definition of monopoly power includes “the ability to exclude competition.”<sup>145</sup> This conduct largely occurred after 2016, so it speaks to Bayer’s ongoing monopoly power rather than Bayer’s monopoly power prior to 2016 when it had EPA and patent protections.

110. My analysis does show a small reduction in Bayer’s market share and prices, and in the overall size of the relevant market (as measured in aggregate doses sold), from 2016 to

<sup>144</sup> For example, as I show, Frontline maintained or increased its price despite generic entry. But I also show a significant loss of sales for Frontline.

<sup>145</sup> *Supra*, n. 133133.

2020, the last year observable. Thus, it may be that Bayer's monopoly power has diminished slightly since its absolute peak. However, all the measures still show evidence of monopoly power, including high market share and ongoing barriers to entry (including Bayer's anticompetitive contracts), supracompetitive prices, and profit margins. Moreover, the overall size of the relevant market continues to be significant and, if anything, the very recent declines in the size of the relevant market suggest successful efforts by Bayer to shift customers from one monopoly product to another product it controls.<sup>146</sup> Finally, to stress again, the key comparison between Bayer's experience and Frontline's illustrates Bayer's successful monopolization versus a more competitive benchmark. For assessing Bayer's ongoing monopoly power, one should focus on Bayer's success in maintaining its sales and lack of competition compared with Frontline's loss of sales and more significant competition at analogous points in time.

## VI. Exclusionary Conduct by Bayer

111. In this section, I expand on my discussion of Bayer's specific conduct that was anticompetitive—Bayer implemented exclusive “no generics” contracts with key wholesale customers that excluded competition from generic copies of its products. Bayer also engaged in other strategies that were consistent with and potentially reinforced the effect of its exclusive contracts. But for those contracts, generic competitors would have been more widely available and made more sales, and in turn, consumers would have benefited from significant cost savings. Bayer's contracts were widespread and worked to maintain Bayer's sales and monopoly position in the relevant antitrust market for imidacloprid spot-ons.

112. To be clear, Bayer's conduct at issue is highly specific and unique to Bayer and this case. Some other facts of this case, generally, follow from common industry practices and are not themselves the anticompetitive conduct at issue—branded pharmaceuticals often have (temporary) protections from competition (e.g., patents); branded pharmaceuticals often have high market share at some point in time; and branded pharmaceuticals may select high prices (well above costs) and choose to maintain those prices over time, despite increased competition. Among other things, Frontline's conduct was highly similar in those respects, and Frontline is not subject to allegations of anticompetitive conduct to my knowledge. Rather, unlike Frontline

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<sup>146</sup> BAH000257075, p. 33.

or other branded pharmaceuticals generally, Bayer set out to create an *additional* barrier to “block” competition. Instead of competing more intensely on price or accepting declining sales (as Frontline did), Bayer instituted its anticompetitive contracts specifically to avoid its economic obligations in a competitive marketplace. In that way, Bayer’s conduct is unique, and the specific conduct at issue is separate and apart from other common practices in the pharmaceutical industry.

### A. Bayer's Strategy to Exclude Generic Competitors

113. Bayer executives pursued a strategy with the specific purpose and effect of limiting competition from generic imidacloprid products. Bayer executives understood that by limiting the quantity and availability of generic imidacloprid spot-ons at large retailers, fewer consumers would see Bayer's high prices directly juxtaposed with generic copy products (i.e., equivalent but cheaper products), and fewer consumers would (or could) "trade-down" from Bayer's products to the cheaper generic versions. Bayer's actions were particularly effective, because, unlike in prescription human pharmaceuticals, substitution to generic spot-on treatments is not mediated by and mandated for pharmacists. By keeping generics off the store shelf (and/or directly comparable side-by-side), Bayer avoided competitive pressure from trade-downs and consumer in-store switching, thereby preserving its higher prices and sales quantities, and earning higher profit at the expense of generic competitors and consumers.

114.

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ATTORNEYS' EYES ONLY**

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117. Besides proliferating exclusive “no generic” contracts with many important wholesale customers, Tevra has alleged that Bayer also engaged in other anticompetitive strategies, including:

- a) A “second brand” strategy, whereby Bayer would offer its own unbranded product at prices below Advantage/Advantix but above generic competitors like Tevra;<sup>154</sup> and
- b) Paid removal of generic competitor products from retailers’ stores.<sup>155</sup>

It is my opinion that both strategies are consistent with Bayer's overall anticompetitive strategy and, where they occurred, they likely helped (or could have helped) reinforce the anticompetitive effects of Bayer's anticompetitive exclusive contracts. That said, it is my understanding that the overall scope of these other strategies was largely duplicative of the same customers covered by Bayer's anticompetitive exclusive contracts.

151

152 *Id.*

<sup>153</sup> BAH000260657-9 at 8, pp. 5-6; BAH000066641-4 at 2; BAH000011099-104; BAH000024718-9; BAH000010156-77.

<sup>154</sup> SAC, § E.1.

<sup>155</sup> SAC, § E.3.

118. Bayer’s alleged “second brand” strategy follows some of the same economic theory as the exclusive contracts just discussed.<sup>156</sup> Where Bayer introduces a second-brand product that is priced above other generic products, and in lieu of (and/or to the exclusion of) a lower priced generic product, it can cause consumers to switch to that higher priced product rather than the cheaper generic version. This partial trade-down by consumers is (a) less in magnitude and (b) Bayer still ultimately retains those switches as sales and profits. By potentially distorting the side-by-side comparison of products, the consumer is left paying more than would have been the case if the consumer traded-down more fully to the lower priced competitor generic product. Thus, the second-brand product benefits Bayer and the retailer through a higher retail sales price (hence, higher retail markup and higher wholesale price), but harms the consumer relative to the situation in which the consumer trades-down more fully to a cheaper product.

119. [REDACTED]

[REDACTED]

<sup>156</sup> Introducing a “second brand” at a lower price is not necessarily anticompetitive. As with any strategy, the impact of the second brand has to be compared with the nature of competition in the absence of Bayer’s second brand, and how the second brand strategy worked in conjunction with Bayer’s other strategies.

<sup>157</sup> SAC, ¶¶ 117-118.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

121. In all, there are multiple clear examples of Bayer’s overall strategy to limit competition from generic imidacloprid spot-ons. By limiting the ability of these generic products to be offered in side-by-side comparison with Bayer’s own products, Bayer avoided head-to-head competition that would have saved consumers money. There is well-understood economic theory that explains why this occurred and why retailers agreed to go along with such strategies, but that does not make them less anticompetitive. Simply put, Bayer expressed a desire to “block generic entry” and then went about a strategy to do so—that is a clear limiting of competition.

### **B. Bayer’s Exclusive Contracts**

122. Given the above discussion, Bayer’s exclusive contracts provide the clearest quantification of the scope of Bayer’s anticompetitive strategies. Where Bayer executed an exclusive contract, generic competitors could not offer their products and, thus, were foreclosed from competing against Bayer. Therefore, I use Bayer’s exclusive contracts—when and where they occurred to my knowledge—to conservatively measure the minimum extent of the relevant market from which Bayer foreclosed competitors and, thus, lessened competition. To be clear, however, this represents the *minimum* extent—it is possible that Bayer’s anticompetitive foreclosure reaches further back in time or to a greater portion of the market, due to Bayer’s other closely related strategies (second brand, paid removal of generics), alleged verbal non-written contracts, or other written contracts beyond the ones I have documented here. To that end, I will update these calculations should there be additional time periods, customers, and/or

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<sup>158</sup> SAC, ¶¶ 155-156.

[illegible]

<sup>159</sup> Also, as noted before, there are examples of these same customers opting to forgo generic imidacloprid spot-on products, but at the same time, they offer both Frontline and generic fipronil spot-ons. *See, supra*, nn. 84-8884.



## VII. Damages

125. But for Bayer's anticompetitive conduct, Tevra and possibly other generic competitors would have made significantly more sales of imidacloprid spot-ons. As is discussed at length above, the view of the but-for world is clear when comparing Bayer's sales history to Frontline's. Whereas Frontline lost the majority of its pre-entry sales to generics, Bayer has successfully retained most of its sales, and generics, including Tevra, have failed to grow in any meaningful way. In this section, I present two estimates of the amount of sales Tevra would have made in the but-for world absent Bayer's anticompetitive conduct. Based on Tevra's pricing and profit margins, Bayer's conduct caused Tevra to lose out on between \$84 and \$109 million in profits from 2017 to 2023.

### A. Tevra's Sales in the But-For World

126. Absent Bayer's anticompetitive contracts, Tevra's generic products would have been purchased by the customers listed previously and, in turn, would have been purchased by consumers. I consider two ways to estimate the amount of wholesale sales Tevra would have made in the but-for world. These estimated but-for sales quantities are shown in **Exhibits 12A and 12B**.

#### 1. Based on Frontline's Sales Decline

127. Both Frontline's historical experience and well-accepted economic theory agree—Bayer would have experienced a much more significant decline in sales quantity if generic imidacloprid products had been able to enter more freely. As is illustrated in **Exhibit 7B**, Frontline lost 57.6% of its sales by 2016 (six years after generic entry) and 64.4% of its sales by 2020 (the latest available data point). Further, as is illustrated in **Exhibit 3B**, generic fipronil products accounted for at least 46.6% of all fipronil doses sold in 2016, implying most of Frontline's sales losses were sales correspondingly gained by generic competitors. This is consistent with the economic literature, in which one study found generic drugs can gain between roughly 65% and 90% of the overall quantity of a drug sold within 12 months of entry,<sup>160</sup> and another study found that the average loss in sales for the branded drug post-generic-entry was 44% overall and that one-third of the branded drugs studied saw a decline in sales of

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<sup>160</sup> Morton and Kyle (2011), pp. 763-823 at Figure 12.5.

65% or more within one to three years.<sup>161</sup> Given these results for Frontline and the literature generally, it is reasonable to think that Bayer's sales would have followed Frontline's in the but-for world. That is, Bayer would have lost 6.0% of its baseline pre-generic-entry sales in 2016 (the first year of entry by its generic competitors), just as Frontline did in 2011 (the first year of entry by its generic competitors).<sup>162</sup> Then, Bayer would have lost 10.6% in 2017, 37.0% in 2018, and so forth, just as Frontline did in its analogous years following entry by its generic competitors. Further, as discussed before, nearly all of the losses for Frontline likely substituted to generic fipronil spot-ons, namely Pet Armor. Thus, it follows that those percentage declines by Frontline estimate both (a) the additional but-for decline for Bayer and (b) the but-for gains by generic versions of Advantage/Advantix.

128. [REDACTED]

[REDACTED]

129. While those estimates give the overall gains in sales to generic competitors, they do not quantify the amount of sales that Tevra would have gained as one such competitor. Here, again, Frontline's history is instructive, as the sales quantities for fipronil spot-ons by 2016 are mainly supplied by one main generic brand within a given sales channel.<sup>164</sup> Given Tevra's extensive efforts to win-over the foreclosed customers,<sup>165</sup> Tevra's equal or lower pricing than

<sup>161</sup> United States Congressional Budget Office. *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, July 1998, p. 28, <https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf> (accessed 8/2/2023).

<sup>162</sup> I set the baseline pre-generic-entry at the 2015 sales number, consistent with the analysis of Frontline's historical decline.

<sup>163</sup> These estimates are conservative in that they omit any incremental sales that came from new consumers (or consumers buying greater quantities). By blocking Tevra from these retailers, Bayer also deprived Tevra of these additional, incremental sales.

<sup>164</sup> See Appendix II, Exhibits B5-B8.

<sup>165</sup> SAC, ¶¶ 132-152.

other generic imidacloprid spot-ons,<sup>166</sup> and other headwinds facing the main other generic competitor,<sup>167</sup> it is reasonable to think Tevra would have been the main (or only) generic to successfully supply the foreclosed customers. Given that, my calculations assume Tevra would have gained all of the sales that Bayer would have lost in the but-for world, yielding a growing volume for Tevra from 0.7 million doses in 2017 to 8.0 million doses by 2023.

## 2. Based on Tevra's Projections

130. Prior to entry, I understand that Tevra had made sales projections.<sup>168</sup> It is my opinion that these are a reasonable cross-reference to also estimate the but-for world. Like all companies, Tevra would have needed to do reasonable due diligence before launching a new product, and I understand the reasonableness of Tevra's projections was demonstrated, among other things, by comparing Tevra's performance for its imidacloprid spot-ons to Tevra's performance when entering with its fipronil spot-on product.<sup>169</sup> More importantly, however, Tevra's projections are in-line with my other estimates.

131. As shown in **Exhibit 12B**, Tevra forecasts implied that it expected to cumulatively sell 18.9 million doses by 2020 and 39.7 million doses by 2023. My estimates discussed above based on Frontline's history imply 13.0 million and 42.8 million cumulative doses at those same points in time. The consistency of Tevra's pre-entry forecasts and the estimates derived from the Frontline "natural experiment" are an informative cross-check in support of both calculation methods.

132. Tevra's incremental sales that it would have gained in the but-for world are simply the difference between its forecast—which it is assumed that Tevra would have attained in the but-for world—and its actual sales to-date. This comparison is shown in the table, illustrating that Tevra would have sold 33.6 million additional doses according to this method.

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<sup>166</sup> See, *supra*, **Exhibit 3C**.

<sup>167</sup> Tabios, Angelee, "PetIQ, Bayer unit resolve patent infringement case over animal products," S&P Global, 1/23/2019, <https://www.spglobal.com/marketintelligence/en/news-insights/trending/KyWQrTBG1VOgJMvPgXuKIA2> (accessed 8/4/2023); "PetIQ, Inc. Announces Amicable Legal Resolution," 1/22/2019, <https://ir.petiq.com/news-releases/news-release-details/petiq-inc-announces-amicable-legal-resolution> (accessed 8/4/2023); see also, SAC, ¶¶ 88-90. Since CAP IM likely owes royalties to Bayer, this is an added cost that Tevra does not have to bear and would make it more difficult, or impossible, for the CAP IM products to price at or below Tevra's products.

<sup>168</sup> SAC, ¶¶ 99 and 214.

<sup>169</sup> SAC, ¶¶ 104-105 and 213.

## B. Tevra's Lost Profits

133. With estimates of Tevra's but-for sales quantities according to the above two methods, it is straightforward to incorporate sales prices and profit margins and compute Tevra's incremental lost profits. Those calculations are presented in **Exhibits 13A to 13B**.

134. I assume that Tevra sells its products at wholesale at its average price based on its limited actual sales over the same period.<sup>170</sup> Tevra's lost revenue is simply its but-for incremental quantity sold multiplied by its average sales price. Then, to convert revenue to profit, I use Tevra's actual gross profit margin (i.e., revenue minus costs of production and delivery) or Tevra's actual direct margin (i.e., gross margin, also minus "direct selling" costs) for the same years.<sup>171</sup> Based on gross margin total incremental lost profit for 2017 to 2023 is between \$103 and \$109 million; based on direct margin, the total incremental lost profit for 2017 to 2023 is between \$84 and \$92 million.

## C. Harm to Consumers

135. While not direct harm to parties in this case, it may be useful to quantify the magnitude of potential harm to consumers. As discussed above, by preventing consumers from trading-down to cheaper generic products like Tevra's, Bayer's conduct causes consumers to pay significantly more than they otherwise could have for essentially the same product. **Exhibit 14** shows the magnitude of those extra consumer expenditures based on Tevra's but-for sales. Assuming other generic competitors, like PetIQ, had similar pricing, the total impact to consumers is potentially more than \$214 million from 2017 to 2023.

## D. Damages After 2020

136. The data provided to me generally only run through mid-2020, and I have presented estimates of damages for 2021 to 2023 based on the available data. I also understand Bayer's conduct and harm to Tevra is ongoing and might extend beyond 2023. Should more recent data become available or if the Court requests damages calculations incorporating

<sup>170</sup> Where Tevra's data are not available, I have estimated Tevra's wholesale prices using Tevra's retail prices shown in **Exhibit 3C** and the average retail-to-wholesale conversions shown in **Exhibit 4C**.

<sup>171</sup> Economically, Tevra would earn the incremental revenue minus its incremental costs of making those sales. Often, that is approximated by the gross margin (i.e., revenue minus the costs of production). To be conservative, I also show the direct margin to account for a scenario in which Tevra incurs some additional incremental "direct" costs beyond the costs of production.

additional data and/or more recent data and/or ongoing harm, the damages estimates discussed above can be updated and/or continued as necessary.

## VIII. Conclusion

137. As outlined in this report, based on my professional training and experience, well-accepted economic theory and principles that I document, and my analysis and review of the economic evidence in this case, it is my expert opinion as a matter of economics that Bayer held monopoly power in the relevant antitrust market for imidacloprid spot-ons until 2016, and then attempted to maintain its monopoly power via anticompetitive exclusive contracts after that point, ultimately harming Tevra, generic imidacloprid competitors more generally, and U.S. consumers. But for Bayer's anticompetitive contracts which had the intent and effect of "blocking generic" competition, Tevra would have been purchased at wholesale (and, in turn, offered at retail) by multiple large customers accounting for almost half the relevant market. Due to foreclosure from these customers, Tevra lost between \$84 and \$109 million in profits from 2017 to 2023 and, as a consequence, consumers were deprived of trade-down opportunities, costing consumers between \$195 and \$214 million in lost savings.



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Paul Wong, Ph.D.

Signed August 9, 2023

## Appendix I. Data

138. In this appendix, I describe the main datasets that I use for analysis in my report: (a) wholesale transaction data supplied by Bayer, (b) wholesale transaction data supplied by Boehringer Ingelheim, and (c) four data sources that can be compiled into a single nationwide retail dataset.

### A. Bayer Wholesale Data

139. [REDACTED]

[REDACTED]

141. The detailed transaction data in aggregate are consistent with the P&L data, suggesting that (a) the transaction data appear reasonably complete and (b) the three Bayer products discussed in the report (Advantage, Advantix, and Seresto) comprise the majority of the revenue (and profits) in the transaction data and a large percentage of Bayer's revenue overall. **Exhibit A1** plots the total net revenue by month from the transaction and P&L data, showing that the transaction data consistently account for more half of the overall P&L data and showing a high correlation in the trend over time between the two data sources.

142. Similarly, the detailed transaction data are also consistent with another dataset (CEESA)<sup>173</sup> that is widely used in the pet medicine industry, providing a secondary confirmation

<sup>172</sup> Bayer produced data for March 2020 to August 2020 relatively late, and I have made my best efforts to review and incorporate these data with the time allotted. Should other details for these months' data prove important to my analyses and ultimate opinions, I will update my analysis accordingly. That said, it is not likely that further updates to these months' data (out of more than 100 analyzed) are likely to significantly affect my opinions.

<sup>173</sup> LINKS-B00000883-8 at 7 ("CEESA is an animal health data clearinghouse that collects net sales revenues by product from its members and redistributes an aggregated market report that provides members with product rankings.").

that the transaction data appear reasonably complete. **Exhibit A2** plots the total net revenue by quarter from the transaction and CEESA data, likewise showing a high correlation in the trend over time for the two data sources.

143.



## B. Frontline Wholesale Data

145. Boehringer Ingelheim (“BI”) is the current owner of Frontline, having acquired Meriel, the brand’s original manufacturer. BI provided wholesale transaction data for Frontline

<sup>174</sup> The structure of Bayer's data for late-March 2020 to August 2020 is different from the rest of the data. I use a similar method to estimate the gross-to-net discount applicable to these months.

that is roughly analogous in structure to Bayer's and shown in the following files:

2009\_Q1\_HIGHLY\_CONFIDENTIAL-2020\_JUL\_AUG\_HIGHLY\_CONFIDENTIAL. These data cover from January 2009 to August 2020, and they show wholesale sales transactions at the invoice/line-item level. I refer to these data as the "Frontline wholesale data" and use these data to measure Frontline's sales quantities, prices, and overall revenues, as discussed in the main text.

146. The detailed Frontline transaction data are also consistent with the CEESA data, helping confirm their completeness and accuracy. **Exhibit A3** plots the total net revenue by quarter from the transaction and CEESA data. As with Bayer's data, these data track the CEESA data closely over time.

147. As discussed in the main text, customers in the Frontline data are lumpy due to Merial/BI's seeming reliance on distributors and middle-men. Because of this and changes in these customers over time, customer-level analysis of Frontline's data is not feasible. Moreover, there is nearly zero overlap between Bayer's customers (who are generally large retailers like Petco and PetSmart) and Frontline's (who are distributors like PetIQ).

### C. Retail Data

148. [REDACTED]

[REDACTED]

<sup>175</sup> [REDACTED]

<sup>176</sup> *Id.*



assume that each data source is synonymous with a specific sales channel as shown in main text. In my report, I refer to the combined dataset of all four sources as the “retail data.”

149. The retail data are consistent with the wholesale Bayer and Frontline data, and with the CEESA data, which helps to confirm their completeness and accuracy. **Exhibits 4B, 4C, and 4E** in the main text show comparisons between the Bayer and Frontline data and the retail data. **Exhibit A4** compares the retail data to the CEESA data where there are matching brands and products across the two datasets. In general, the wholesale and retail data are proportional to one another in expected magnitudes, and the various datasets are consistent with each other across brands/products and across time within a brand/product.

150. [REDACTED]

[REDACTED]

151. As is shown in the main text, there are times in which I use the retail data that I observe to estimate the corresponding wholesale data I do not observe directly, and vice versa. Where I do so, I convert quantities and prices based on the Bayer and Frontline products that I observe in both the wholesale and retail data. Generally, these conversions require one to adjust upward the dose quantities when moving from the retail data to the wholesale data (i.e.,

177 [REDACTED]

wholesale doses are greater than retail doses) and adjust downward the prices when moving from the retail data to the wholesale data (i.e., retail prices are marked-up such that wholesale prices are significantly less than retail prices).

## **Appendix II. Retail Sales by Data Source**

152. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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## PAUL WONG MANAGING DIRECTOR

Dr. Wong is a member of NERA's Health Care and Life Sciences practice, and NERA's Antitrust and Competition practice. Since joining NERA, Dr. Wong has consulted on a variety of health care mergers, including the *Advocate-NorthShore* and *Jefferson-Einstein* hospital mergers challenged by the Federal Trade Commission, the *Aetna-Humana* and *Centene-Health Net* health insurance mergers, as well as mergers involving major provider systems in more than 20 states. Dr. Wong has also consulted on antitrust litigations in health care and other industries, including those involving hospitals, multispecialty physician groups, health insurers, health IT providers, laboratories, medical devices, medical supply distribution, and hospital equipment supply and rental. Of note, Dr. Wong was the lead consultant for *USA v. Carolinas Healthcare System*, involving "steering provisions" in hospital reimbursement contracts, *State of Washington v. Franciscan Health System*, involving the challenge of two consummated acquisitions of physician groups, and *FTC v. Surescripts*, involving the challenge of loyalty discounts in the electronic-prescribing health IT industry.

Prior to joining NERA, Dr. Wong received a Ph.D. and an M.A. in Economics from Stanford University, and a B.A. in Business Economics from University of California Los Angeles (UCLA). Dr. Wong has professional experience in healthcare services research and healthcare analytics from his prior work at Palo Alto Medical Foundation Research Institute, and experience as an investment manager from his prior work at Brandes Investment Partners.

In addition, Dr. Wong has taught economics at the Anderson Graduate School of Management at the University of California Riverside (UCR). Dr. Wong has also conducted academic research on a variety of healthcare and antitrust issues, and published articles in journals such as *Population Health Management*, *Loyola University Chicago Law Journal*, *Antitrust Chronicle*, and *Competition*. Notably, Dr. Wong has written multiple papers analyzing competition and regulation in the US health insurance industry. As well, Dr. Wong has researched the impact of patient-centered care on patients' medical costs, and how competition impacts patenting and innovation in agricultural biotechnology. Dr. Wong has presented seminars to a number of organizations, including the US Department of Justice, the American Society of Health Economists, the American Health Lawyers Association, the American Bar Association, and the Indiana State Legislature.

**Exhibit 1****Education**

2015	<b>Stanford University</b> Department of Economics Ph.D., Economics
2015	<b>Stanford University</b> Department of Economics M.A., Economics
2008	<b>University of California, Los Angeles</b> Department of Economics B.A. (summa cum laude), Business Economics

**Professional Experience**

2023-pres.	<b>NERA Economic Consulting</b> Managing Director
2021-2023	Director
2019-2021	Associate Director
2016-2019	Senior Consultant
2015-2016	Consultant
2018-2020	<b>University of California, Riverside</b> <b>A. Gary Anderson Graduate School of Management</b> Lecturer
2012-2015	<b>Stanford University</b> <b>Department of Economics</b> Teaching Assistant
2013-2015	<b>Palo Alto Medical Foundation Research Institute</b> Research Assistant
2008-2010	<b>Brandes Investment Partners</b> Research Associate

**Testimony and Expert Disclosures**

2023	<i>Los Alamitos Medical Center, et al. v. Kaiser Foundation Hospitals and Kaiser Foundation Health Plan, Inc.</i> , JAMS, Expert Deposition of Dr. Paul Wong, March, 10, 2023.
2022	<i>Indiana State Legislature, Interim Study Committee on Public Health, Behavioral Health, and Human Services</i> , Testimony Re: Healthcare Provider Market Structure, Market Concentration, Pricing, and Competition, October 20, 2022.

**Exhibit 1**

- 2021 *NRT Technology Corp. and NRT Technology, Inc. v. Everi Holdings, Inc. and Everi Payments, Inc.*, D. Del., Declaration of Dr. Paul Wong In Support of Plaintiffs' Motion to Compel Production of Documents and Data by Defendants, May 16, 2021.
- Huntington Hospital and Cedars-Sinai Health System v. California Department of Justice and Matthew Rodriguez*, Superior Court of California, County of Los Angeles, Expert Report by Dr. Paul Wong, March 29, 2021.
- Canopy Health v. Western Health Advantage*, JAMS, Expert Testimony of Dr. Paul Wong, February 1, 2021.
- 2020 *Canopy Health v. Western Health Advantage*, JAMS, Expert Deposition of Dr. Paul Wong, December 22, 2020.
- Terri Blackburn v. Bellingham Anesthesia Associates*, JAMS, Expert Report of Dr. Paul Wong, December 9, 2020.
- 2019 *Jason Toranto v. Daniel Jaffurs, Amanda Gosman, Rady Children's Hospital-San Diego, Rady Children's Specialists of San Diego, Rady Children's Medical Staff, Children's Hospital of Orange County, and CHOC Medical Staff*, S.D. Cal., Expert Deposition of Paul Wong, Ph.D., June 7, 2019.
- 2018 *State of Washington v. Franciscan Health System, et al.*, W.D. Wash., Declaration of Dr. Paul Wong In Support of Defendant Franciscan's Motion to Compel Production of Documents by First Choice Health Network, Inc., March 19, 2018.
- 2017 *State of Washington v. Franciscan Health System, et al.*, W.D. Wash., Declaration of Dr. Paul Wong In Support of Certain Defendants' Motion to Postpone Briefing on Plaintiff's Motion for Partial Summary Judgment, December 15, 2017.
- 2016 *In the Matter of: The Proposed Acquisition of Control of Health Net Life Insurance Company and Health Net, Inc. by Centene Corporation and Chopin Merger Sub I, Inc. and Chopin Merger Sub II, Inc.*, CA Department of Insurance, Written Testimony of Dr. Lawrence Wu and Dr. Paul Wong, File No. App-2015-00889, January 15, 2016.

**Expert Engagements**

- 2019 *Indiana Hospitals Do Not Have a "Monopoly Problem"*: Independent report commissioned by the Indiana Hospital Association analyzing hospital concentration and competition in Indiana.
- 2018 *Mat-Su Valley Medical Center, LLC v. State of Alaska*: Analysis of outpatient health care markets related to an ambulatory surgery center's Certificate of Need in Wasilla, AK.

## Consulting Engagements

*21<sup>st</sup> Century Oncology, Inc. v. The Honorable Ashley B. Moody, in her official capacity as the Attorney General of the State of Florida, and the Honorable Laurel M. Lee, in her official capacity as Secretary of the Florida Department of State*: Challenge of Florida Statute 542.336 invalidating restrictive covenants (e.g., non-compete agreements) in physician contracts, alleging the statute was unconstitutional.

*3B Medical, Inc. v. ResMed Corp.*: Alleged foreclosure of the market for sleep apnea durable medical equipment due to a tying scheme involving sleep apnea ventilator machines and other related equipment.

*Adventist Health System – Bert Fish Medical Center*: Merger of hospitals in New Smyrna Beach, FL.

*Adventist Health – Beverly Hospital*: Acquisition of a failing hospital and investigation by the California Attorney General's office.

*Advocate Health – NorthShore University Healthsystem*: FTC challenge and merger litigation involving two hospital systems in Chicago, IL.

*Aetna, Inc. – Humana, Inc.*: Proposed merger of two health insurers. Investigation (initial and second request phases), DOJ challenge, and merger litigation of two nationwide health insurers.

*Ascension Health – Wheaton Franciscan Healthcare*: Merger of two hospital systems in Milwaukee, WI.

*Aspirus Health Care – Ascension Health*: Merger of seventeen hospitals in northern Wisconsin and Michigan.

*Centene Corporation – Health Net, Inc.*: Merger of two large health insurers with national but complementary footprints (see written testimony).

*CHI Franciscan – Virginia Mason*: Merger of hospitals and physicians in Washington state.

*CHRISTUS – Trinity Mother Frances*: Merger of hospitals and physicians in Tyler, TX.

*CHRISTUS – Good Shepherd*: Merger of hospitals and physicians in Longview, TX.

*DiCesare, et al. v. Carolinas Healthcare System*: A class-action litigation mirroring allegations in *United States of America and the State of North Carolina v. Carolinas Healthcare System* (see below).

**Exhibit 1**

*FTC v. Surescripts, LLC*: Allegations that Surescripts' loyalty discounts foreclosed competitors and inhibited competition in the two-sided electronic prescribing markets for routing and eligibility in violation of Section 2 of the Sherman Act.

*Hackensack University Health Network – Meridian Health*: Merger of two large hospital systems in NJ.

*Hill Physicians – Muir Medical Group IPA*: Affiliation of two independent practice associations involving nearly 5,000 physicians.

*Hurst International v. Sinclair Systems International*: Alleged predatory pricing by a large fruit labeling equipment and supply manufacturer and distributor.

*Jefferson Health – Einstein Healthcare Network*: FTC challenge and merger litigation involving two hospital systems in Philadelphia, PA.

*Labcorp – Ascension Health*: Acquisition of hospital-based laboratories across ten states by a national lab services provider.

*Lafayette General Health – Regional Medical Center of Acadiana (an HCA hospital)*: Merger of hospitals in Lafayette, LA.

*Marshfield Clinic Health System – Ascension Health*: Merger of hospitals in Wausau, WI.

*Memorial Hospital at Gulfport – Merit Health Biloxi (part of Community Health Systems)*: joint venture between two hospital systems in Biloxi, MS.

*MultiCare – Capital Medical Center*: Acquisition of a hospital by a health system in Olympia, WA.

*NRT v. Everi (f.k.a., Global Cash Access)*: Alleged patent fraud, monopolization, and foreclosure of the market for in-casino cash access kiosks.

*OMNI Healthcare, Inc., et al. v. Health First, Inc., et al.*: Alleged monopolization and tying by a vertically integrated health system (insurance, hospitals, physicians) in an effort to foreclose the market for physician services.

*Oregon Potato Company – NORPAC*: Merger of two frozen vegetable processors in Western Oregon, one of which was a failing firm. Investigation of buyer (monopsony) and seller (monopoly) concerns by the DOJ.

*PeaceHealth – Pacific Rim Outpatient Surgery Center*: Acquisition of ambulatory surgery center by a hospital system.

*Providence Health & Services – St. Joseph Health*: Merger of two hospital systems, creating one of the ten largest nonprofit hospital systems in the U.S.

**Exhibit 1**

*Providence Saint Joseph Health – Adventist Health:* Merger of eight hospitals in Northern California.

*Sanford Health – UnityPoint Health:* Merger of two large hospitals systems spanning seven states.

*Schuylkill Health System, et al. v. Cardinal Health, LLC and Owens & Minor Distribution, Inc.:* Alleged overpayment as a result of a foreclosure scheme in markets for the distribution of hospital supplies, including suture and endo products.

*Sonic Healthcare USA – ProPath:* Merger of two clinical and pathology laboratories.

*St. Agnes Medical Center (a Trinity Health hospital) – Madera Community Hospital:* Acquisition of a failing hospital and investigation by the California Attorney General's office.

*State of Washington v. Franciscan Health System, et al.:* Challenge of Franciscan's acquisition of two physician groups in Kitsap, WA (The Doctors Clinic and WestSound Orthopaedics), alleging the acquisitions were unlawful under Section 1 of the Sherman Act and Section 7 of the Clayton Act.

*SUNY Upstate Medical University – Crouse Hospital:* Hospital merger, Certificate of Public Advantage (COPA) application, and investigation by the New York Department of Health.

*The Wonderful Company v. Anthem Blue Cross and Lucile Packard Children's Hospital:* Alleged monopolization by a nationally-renowned children's hospital and alleged conspiracy by the children's hospital and a large insurer.

*UnitedHealth Group/Optum – DaVita Medical Group:* National merger of United (a diversified healthcare company with insurance and physicians) and DaVita (physicians). Review of vertical merger issues (insurance-to-physician) in Colorado Springs, CO, and vertical and horizontal issues (insurance-to-physician and physician-to-physician) in Las Vegas, NV.

*United States of America and the State of North Carolina v. Carolinas Healthcare System:* Allegations that CHS's commercial insurance contracts prohibited innovation in insurance products and limited hospital competition in Charlotte, NC in violation of Section 1 of the Sherman Act.

*Universal Hospital Services, Inc. v. Hill-Rom Holdings, Inc.:* Alleged foreclosure in markets involving rental hospital equipment (specialty beds and other durable equipment) due to a tying scheme combining equipment rentals and the purchase of hospital beds.



**Exhibit 1**

*University of Wisconsin Health/Unity-Gundersen Health Insurance – UnityPoint-Meriter/Physicians Plus Insurance Corporation*: Merger of two vertically integrated health systems (insurance, hospitals, physicians) in Madison, WI, involving the simultaneous merger of provider-owned health plans, multispecialty physician groups, and hospitals.

*Wilson N. Jones Memorial Hospital v. Texas Health Resources and LHP Hospital Group, Inc.*: Market analysis in litigation concerning an alleged breach of contract.

**Publications**

- 2020 “Non-Compete Agreements: Might They Be Procompetitive in Healthcare?” *Antitrust Chronicle*, Competition Policy International (May 2020), with Yun Ling and Emily Walden.
- 2018 “Mini-Roundtable: Expert Witness in Competition Disputes,” *Corporate Disputes Magazine*, (April-June 2018), with David Blackburn, Nathan Blalock, and Subramaniam Ramanarayanan.
- “Uncertainty and Scientific Complexity: An Introduction to Economic Forces that Drive Current Debates in Health Care Antitrust,” *Competition, Antitrust and Unfair Competition Law Section of the State Bar of California*, Vol. 27, Num. 1 (2018).
- 2017 “The Hypothetical Monopolist Test: Is There a ‘Preferred’ Method?” *Antitrust Health Care Chronicle*, American Bar Association Antitrust Section, Vol. 31, Num. 3 (2017), with Subramaniam Ramanarayanan.
- “Health Care Antitrust: Are Courts Adapting to a Complex and Dynamic Industry or Are They Making Exceptions?” *Loyola University Chicago Law Journal*, Vol. 48, Num. 3 (2017), with Lawrence Wu.
- “Features of Patient-Centered Primary Care and the Use of Ambulatory Care,” *Population Health Management*, Vol. 20, Num. 4 (2017), with Ming Tai-Seale and Laura Panattoni.

**Working Papers**

- “Entry and Long-Run Market Structure in Nongroup Health Insurance.”
- “Studying State-Level Variation in Nongroup Health Insurance Regulation: Insurers’ Incentives to Screen Consumers.”
- “Competition and Innovation: Evidence from Patents and Field Trials for Genetically Modified Crops,” with Petra Moser.

**Invited Presentations**

- 2022 “Implications for Merger Enforcement from Recent Federal Court Decisions Related to Healthcare and Technology,” via Webinar, American Bar Association Section of Antitrust Law.
- “AHLA’s Speaking of Health Law: Key Takeaways from *Sidibe v. Sutter*,” via Webinar, American Health Lawyers Association.
- 2021 “Navigating Payer-Provider Contracts: Spotting the Antitrust Issues,” via Webinar at Virtual Health Care Antitrust: Meeting the Challenge, American Health Lawyers Association.
- “#116 Can Non-Competes Be Procompetitive?: An Economist’s View – Our Curious Amalgam,” via Webinar, American Bar Association Section of Antitrust Law.
- 2020 “#93 Who Is Ready for 2021? Year in Review: Part 1 – Our Curious Amalgam,” via Webinar, American Bar Association Section of Antitrust Law.
- “Winds of Change? Reactions to the Vertical Merger Guidelines and a Lookback at Prior Deals,” via Webinar, American Bar Association Section of Antitrust Law.
- “Making a Comment: Perspectives on the ABA Comment to the Agencies’ Draft Vertical Merger Guidelines,” via Webinar, American Bar Association Section of Antitrust Law.
- “Antitrust Issues in Physician-Hospital Alignment,” at the Physicians and Hospitals Law Institute, American Health Lawyers Association, Phoenix, AZ.
- 2019 “Steering Your Clients Right: Are Anti-Steering Contracts Permissible?” at the Antitrust & Trade Regulation Seminar, NERA Economic Consulting, San Diego, CA.
- 2018 “Ch-Ch-Changes: Analyzing Vertical Arrangements Reshaping Healthcare,” at the Antitrust & Trade Regulation Seminar, NERA Economic Consulting, Bachelor Gulch, CO.
- “Cutting Edge Economic Issues: Real World Application – Two-Stage Bargaining Models, Vertical Integration, and Cross-Market Merger Effects,” at the American Bar Association and American Health Lawyers Association Antitrust in Health Care Conference, Pentagon City, VA.
- 2017 “Too Big to Pass? Lessons from the Health Insurance Mega-Merger Challenges,” at the Antitrust & Trade Regulation Seminar, NERA Economic Consulting, San Diego, CA.

**Exhibit 1**

- 2016 “Cross-Market Mergers in the Healthcare Industry: The New Focus of Antitrust Scrutiny,” via Webinar, The Knowledge Group.
- “Developments in Hospital Merger Analysis: Competitive Effects Analysis in the Advocate-NorthShore Case,” at the Antitrust & Trade Regulation Seminar, NERA Economic Consulting, Park City, UT.
- 2015 “Defining Healthcare Markets,” at Sheppard, Mullin, Richter & Hampton LLP, Los Angeles, CA.
- “Entry and Long-Run Market Structure in Nongroup Health Insurance,” at the U.S. Department of Justice, Washington, DC.
- “Entry and Long-Run Market Structure in Nongroup Health Insurance,” at the U.S. Congressional Budget Office, Washington, DC.
- “Entry and Long-Run Market Structure in Nongroup Health Insurance,” at Seattle University, Department of Economics, Seattle, WA.
- 2014 “Associations Between Features of Patient-Centered Primary Care and Patients' Use of Ambulatory Care,” at the American Society of Health Economists, Biennial Conference, Los Angeles, CA.

**Honors and Recognition**

- 2011 Amos Warner Research Associate, Stanford University
- 2010 Stanford University Economics Fellowship, Stanford University
- 2008 Phi Beta Kappa, Eta Chapter of California, UCLA
- National Society of Collegiate Scholars, UCLA
- ALD/PES Honor Society, UCLA
- Professor Harry Simons Economics Scholarship, UCLA
- 2007 Howard J. and Mitzi W. Green Economics Scholarship, UCLA

**Professional Service**

- 2021-pres. Healthcare and Pharmaceuticals Committee, Antitrust Section, American Bar Association
- 2018-2021 Mergers and Acquisitions Committee, Antitrust Section, American Bar Association

**Exhibit 2**  
**Materials Relied Upon**

**Bates Numbered Documents**

BAH000000041-59	BAH000000612-23	BAH000100703-11
BAH000000060-73	BAH000000624-35	BAH000101787
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PW-B0020180\_Highly Confidential - Attorneys' Eyes Only-c.XLSX

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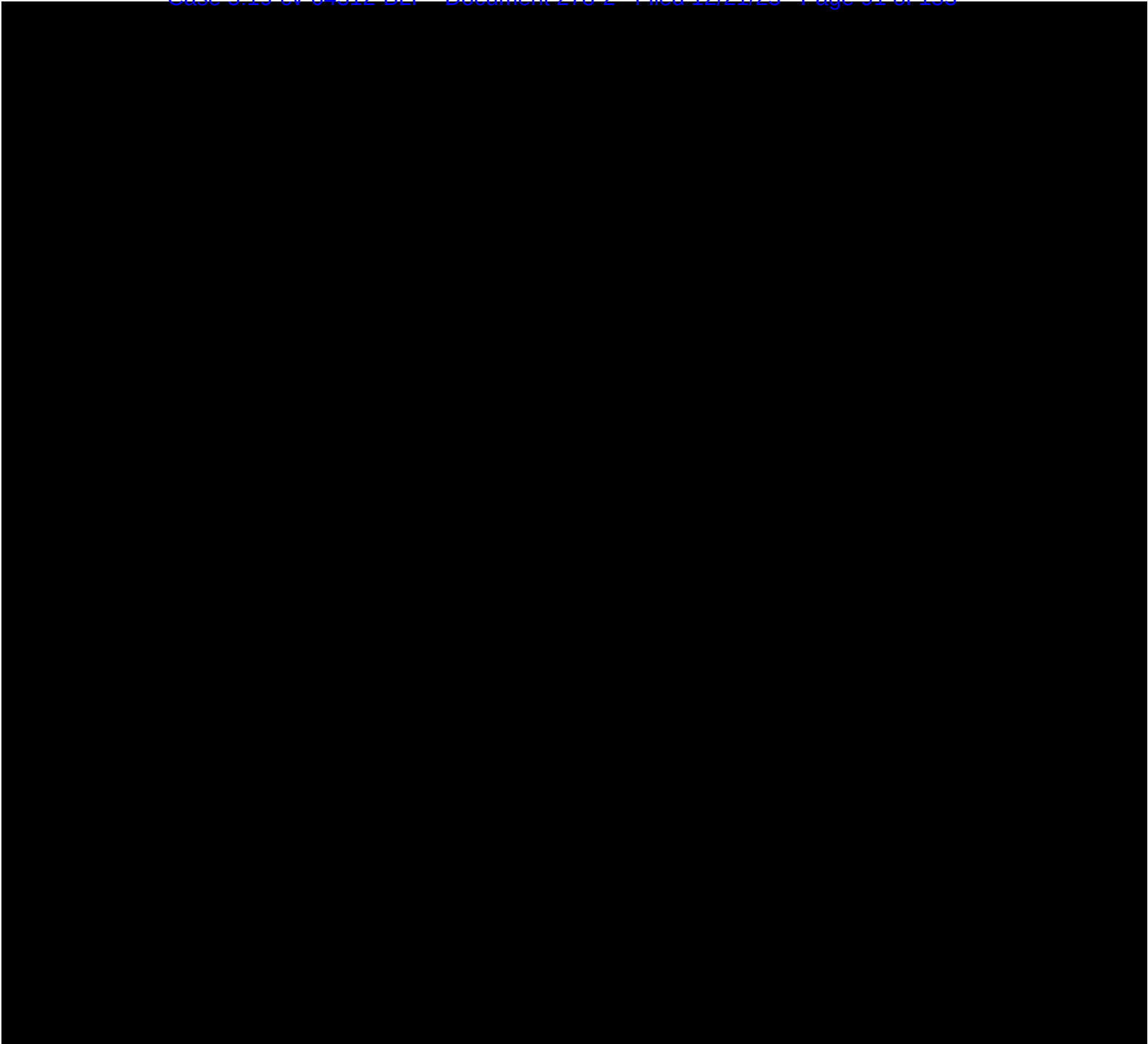
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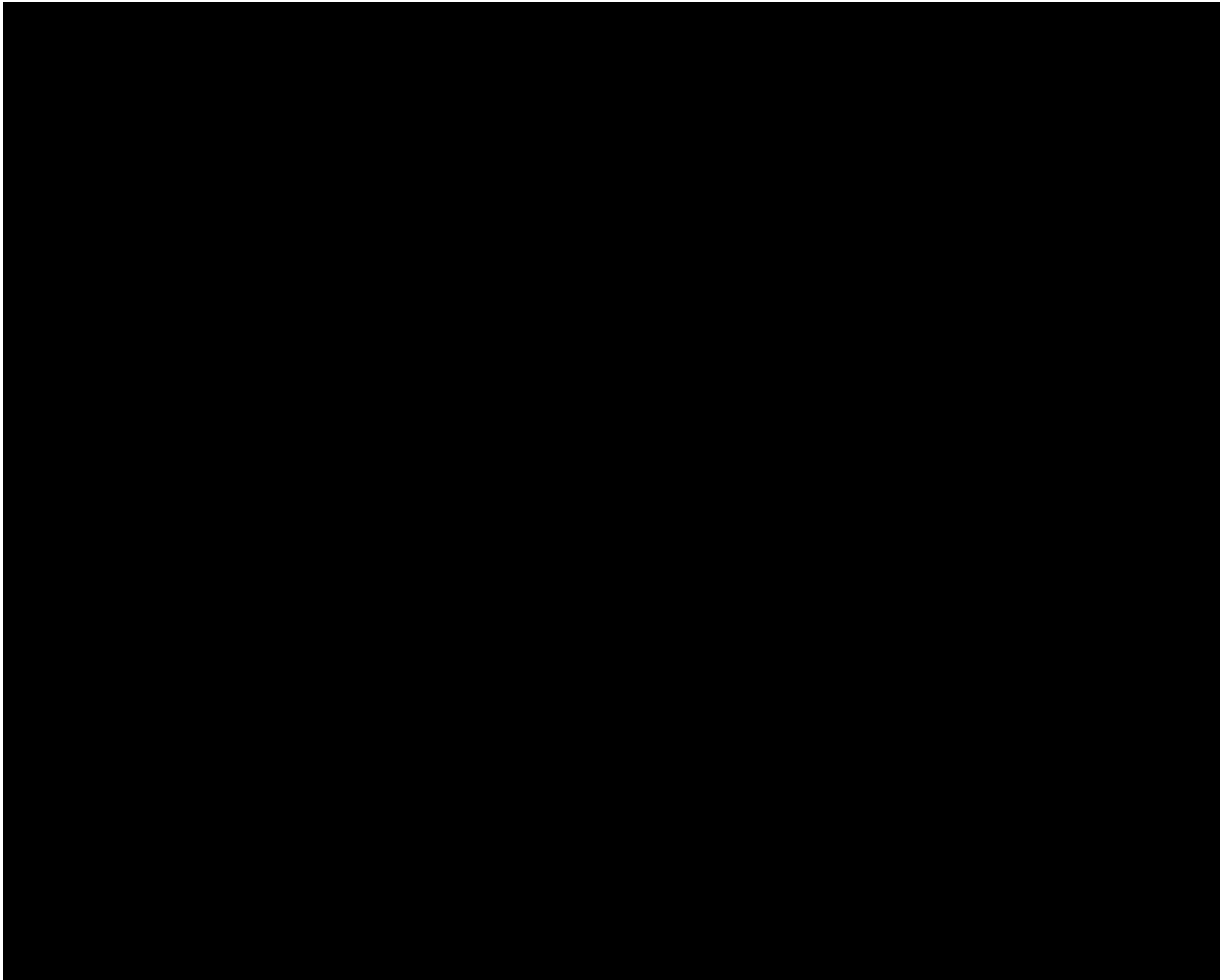
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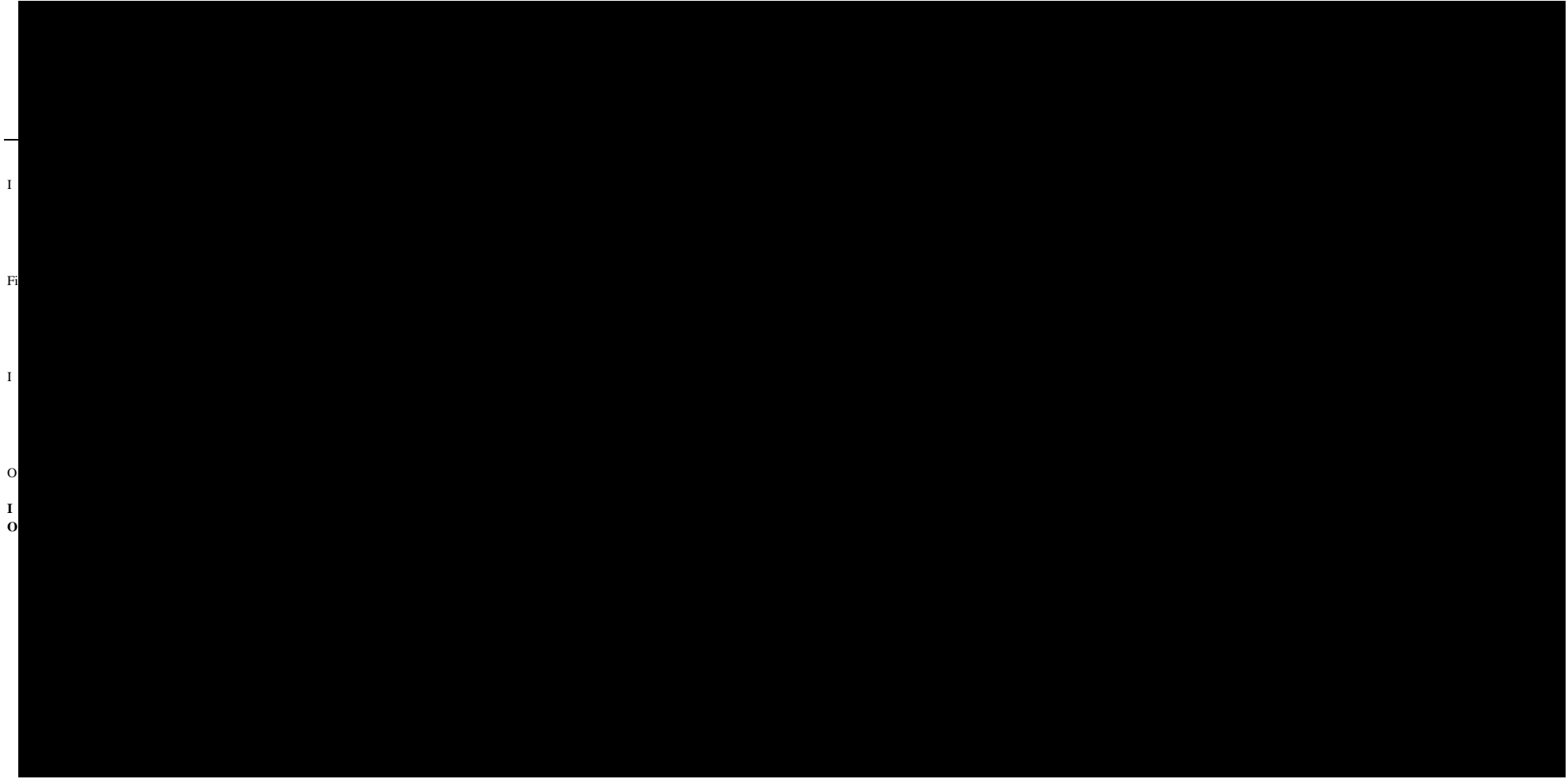
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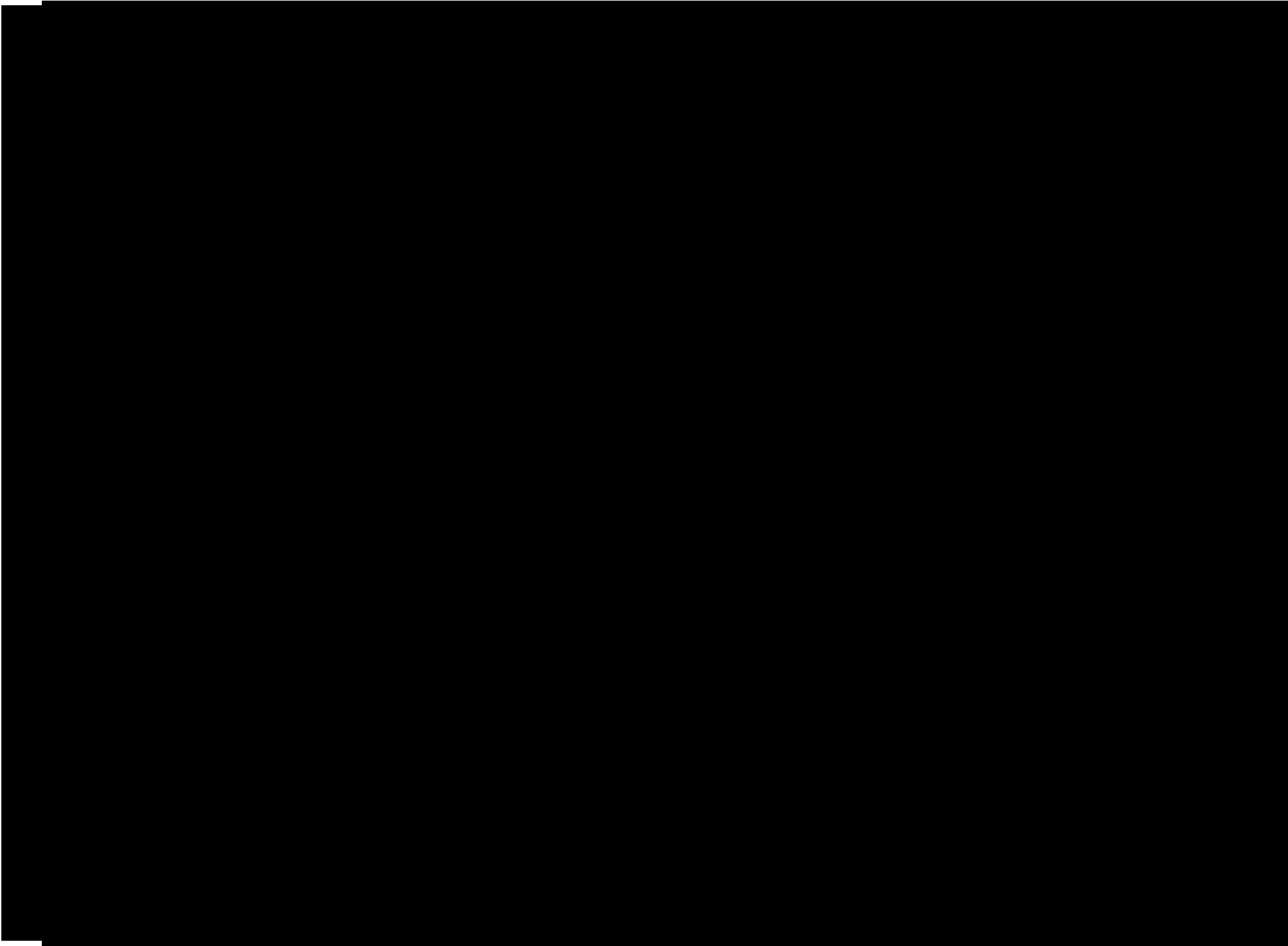


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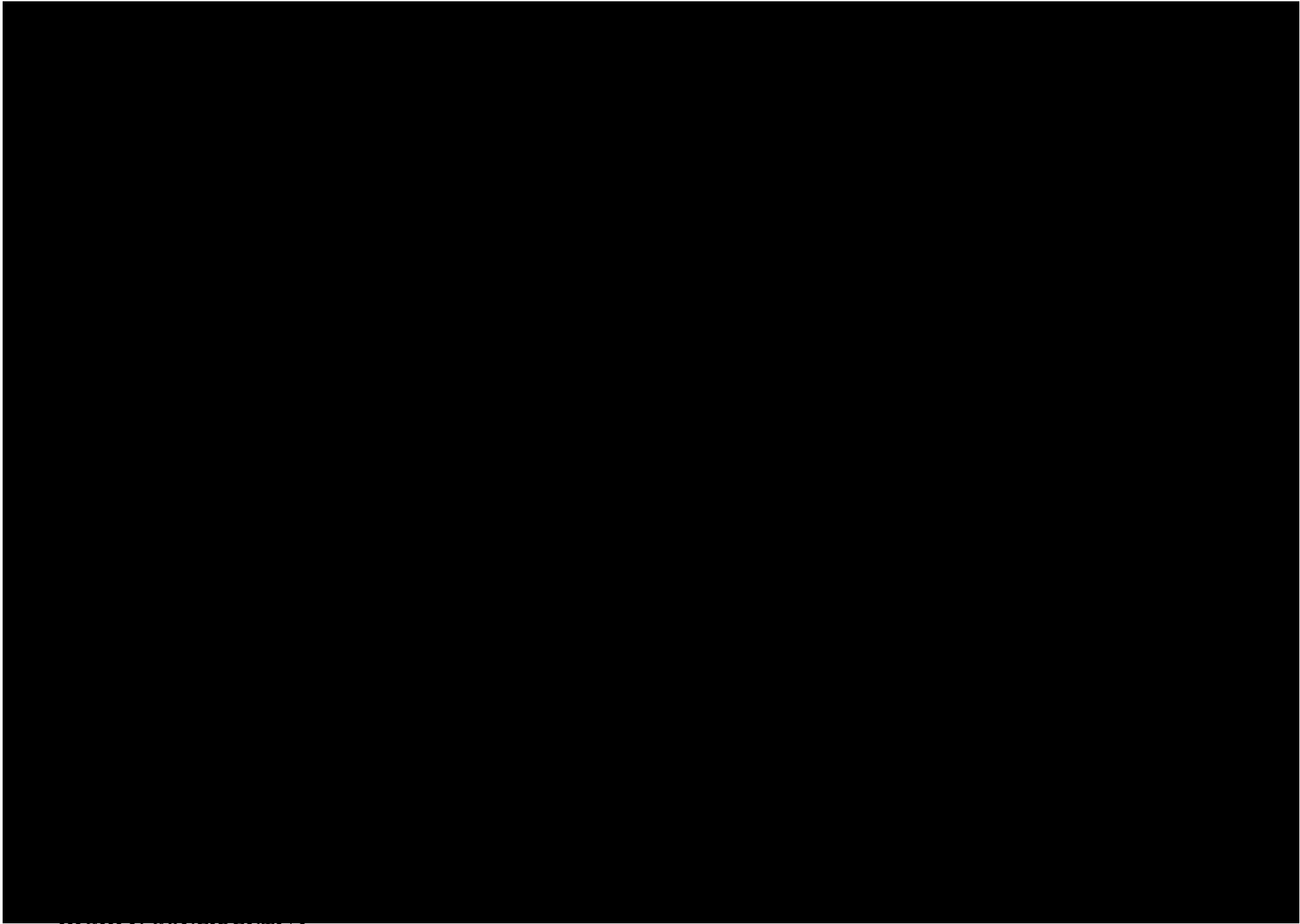


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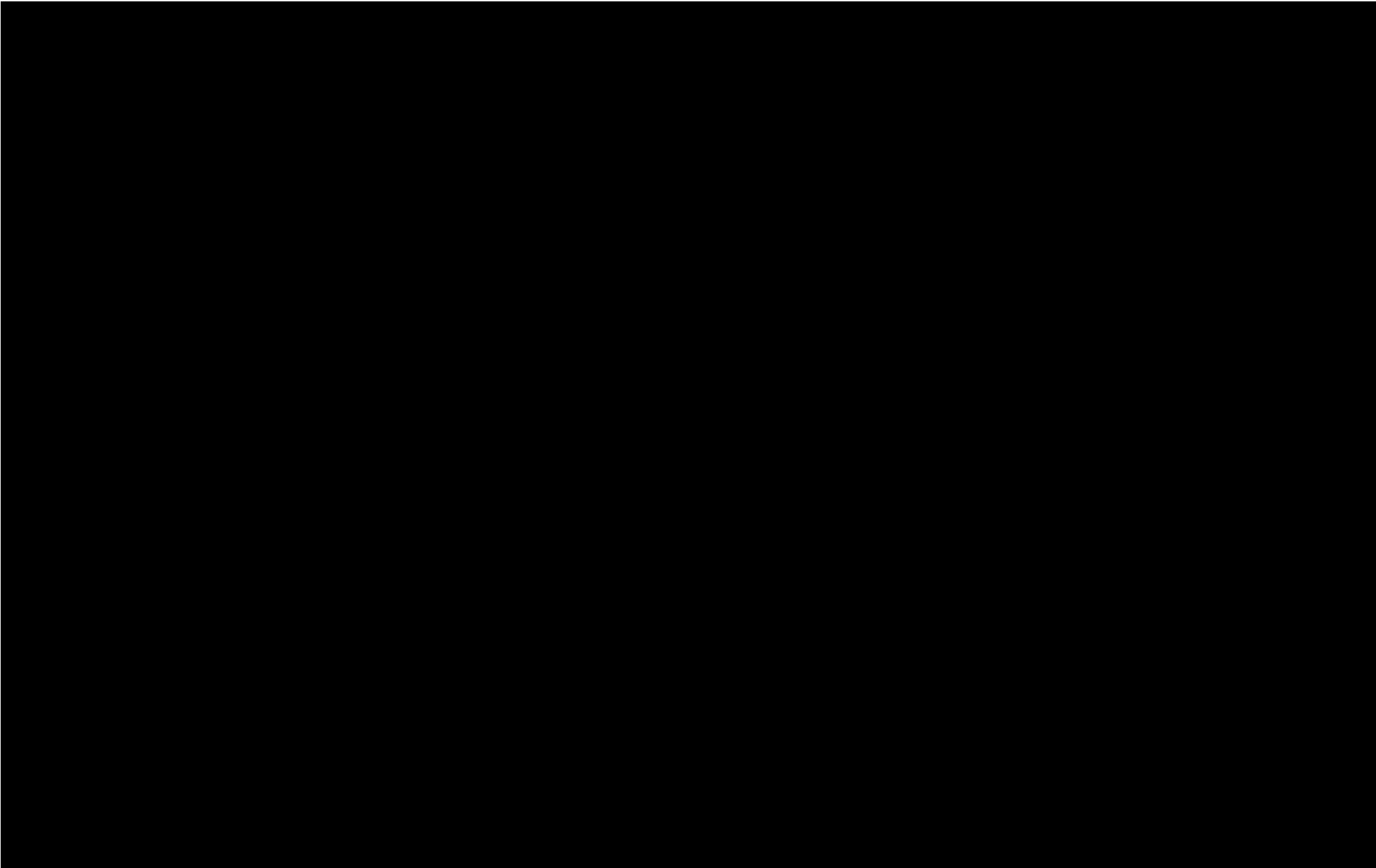




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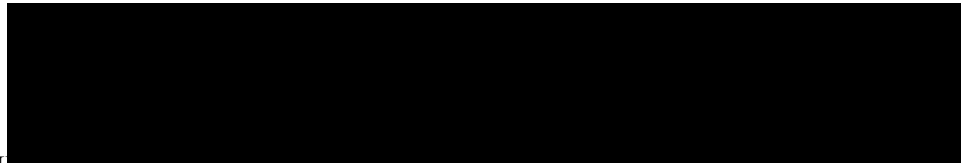
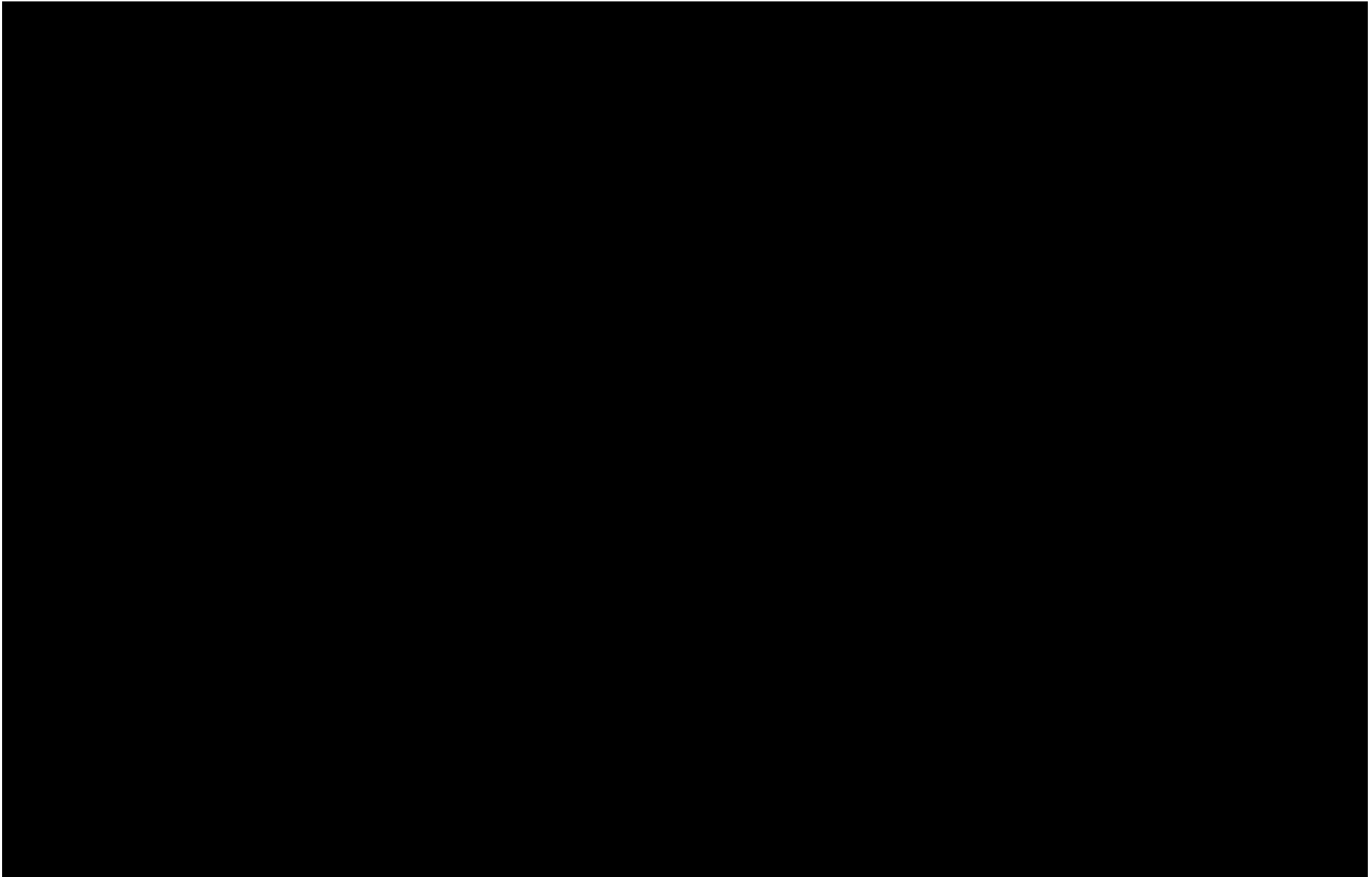


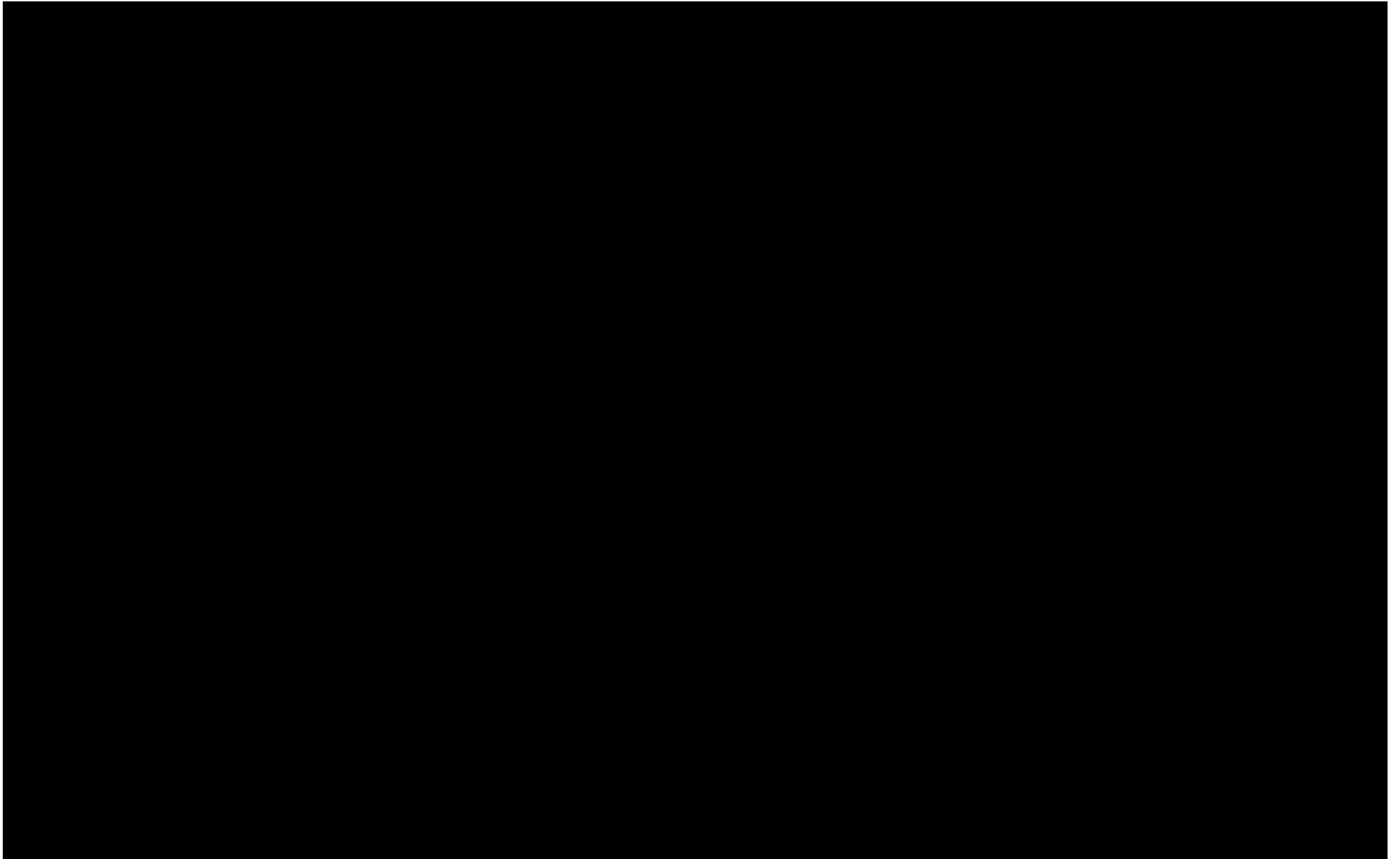
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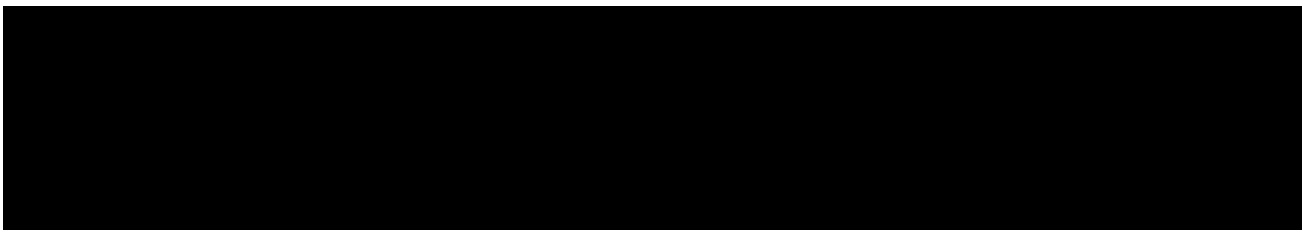
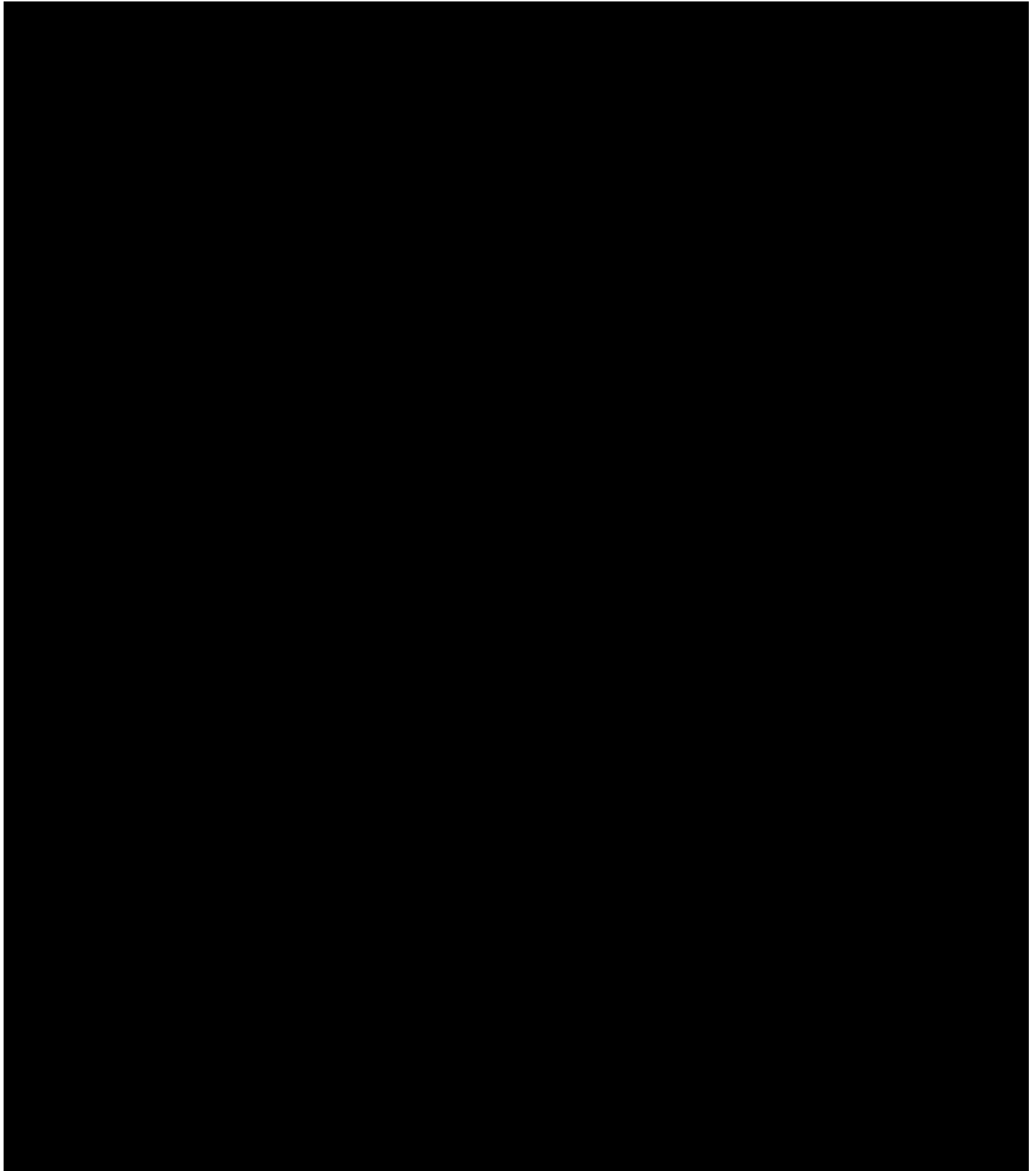
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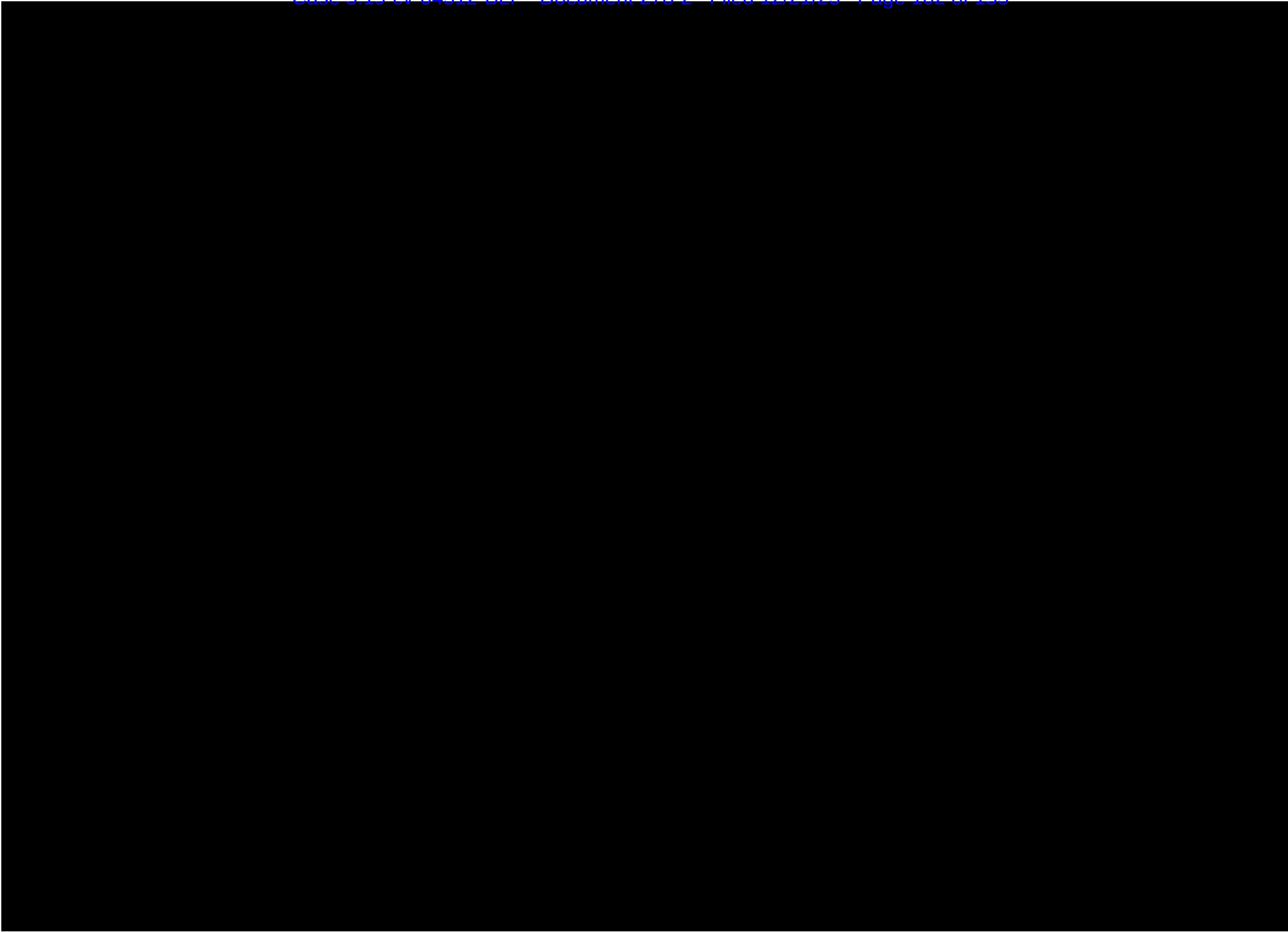
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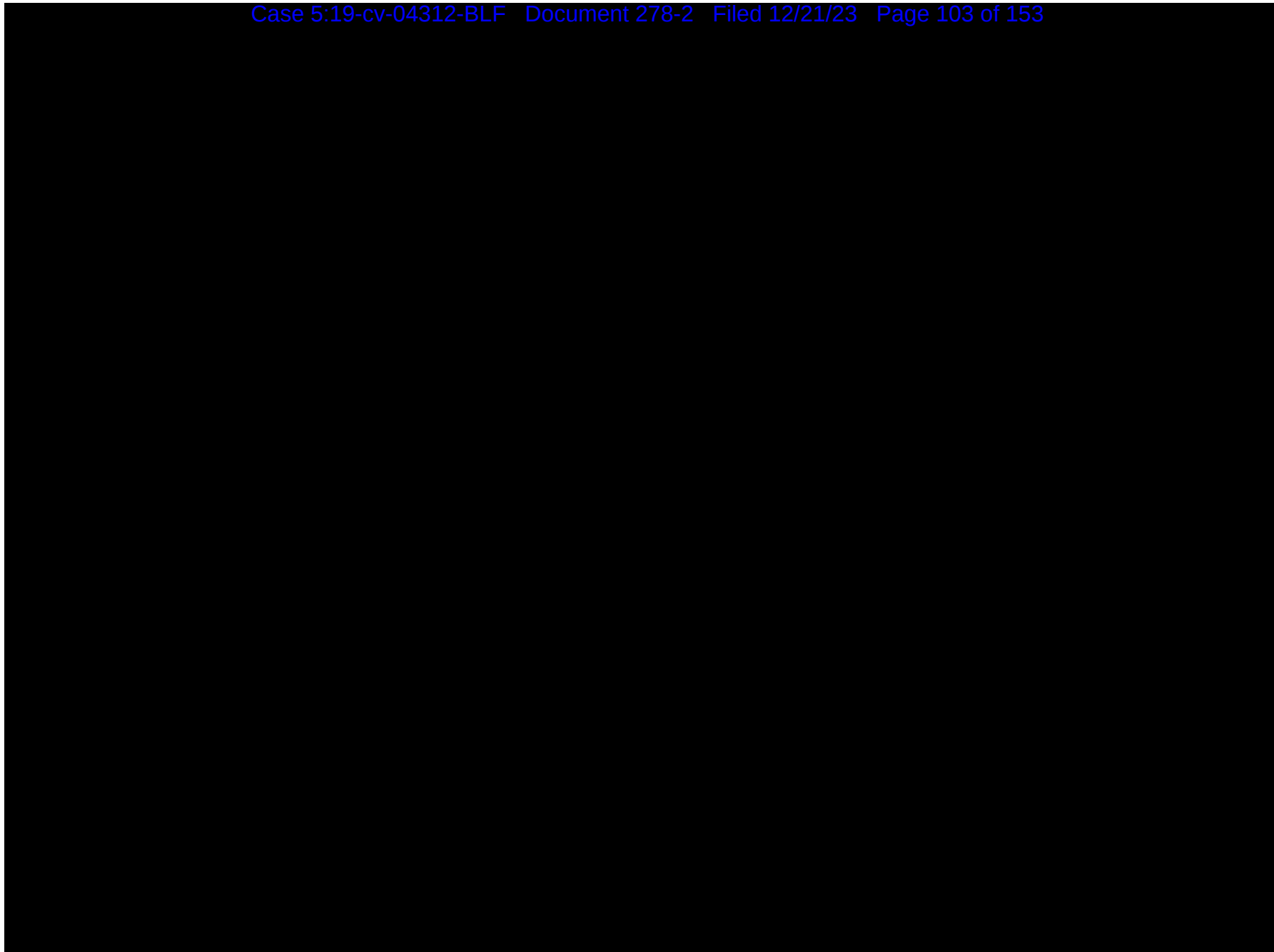


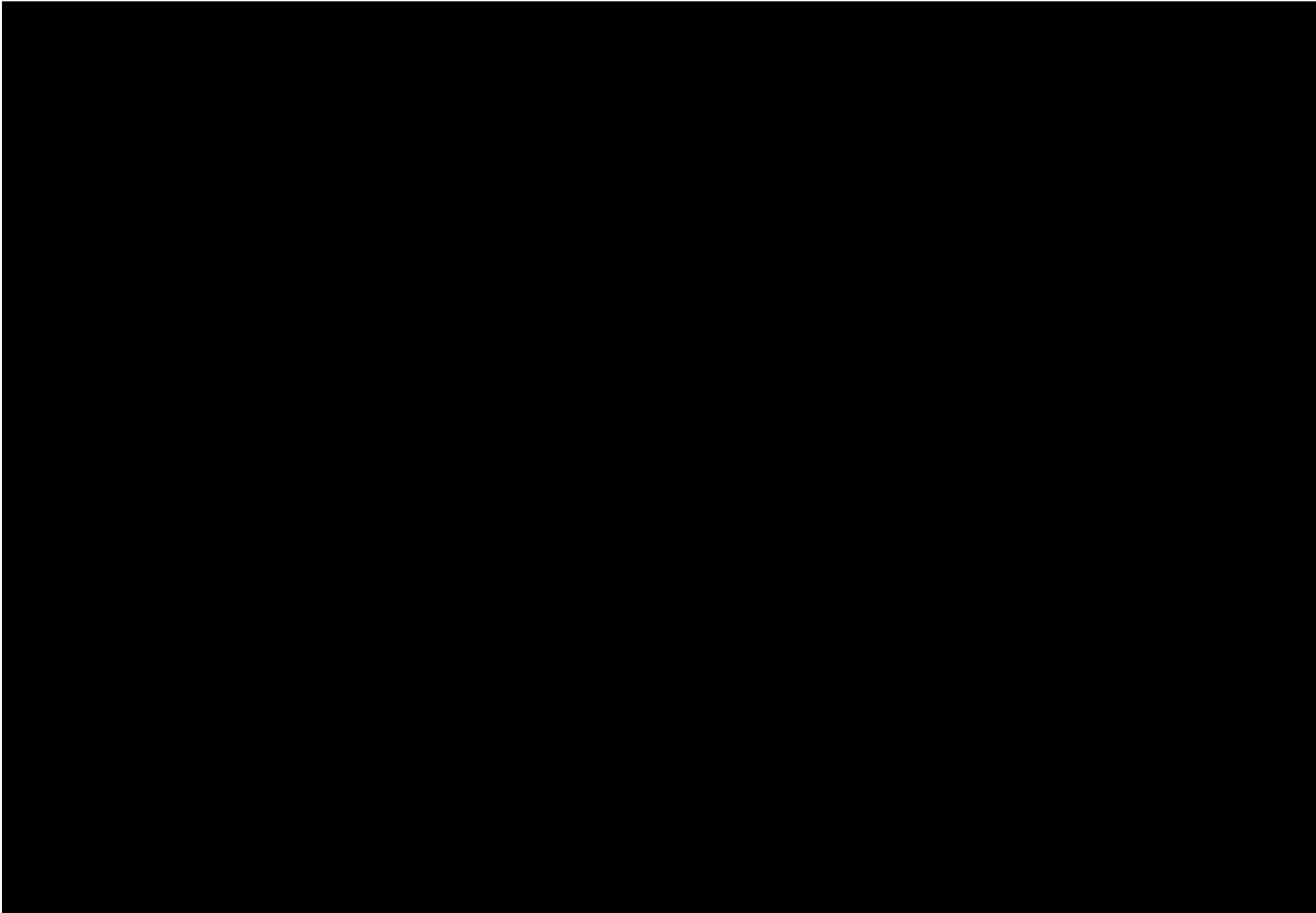
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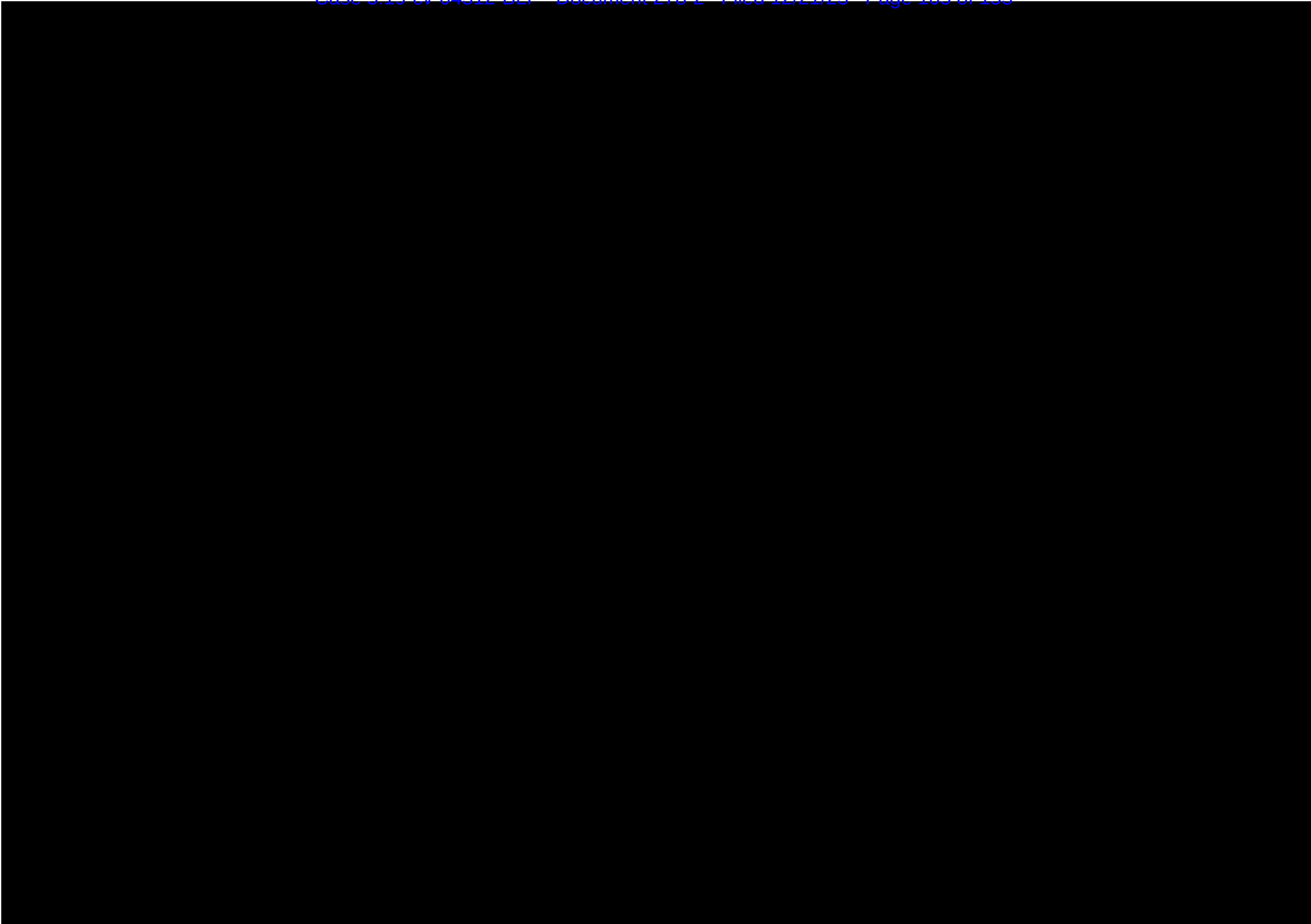
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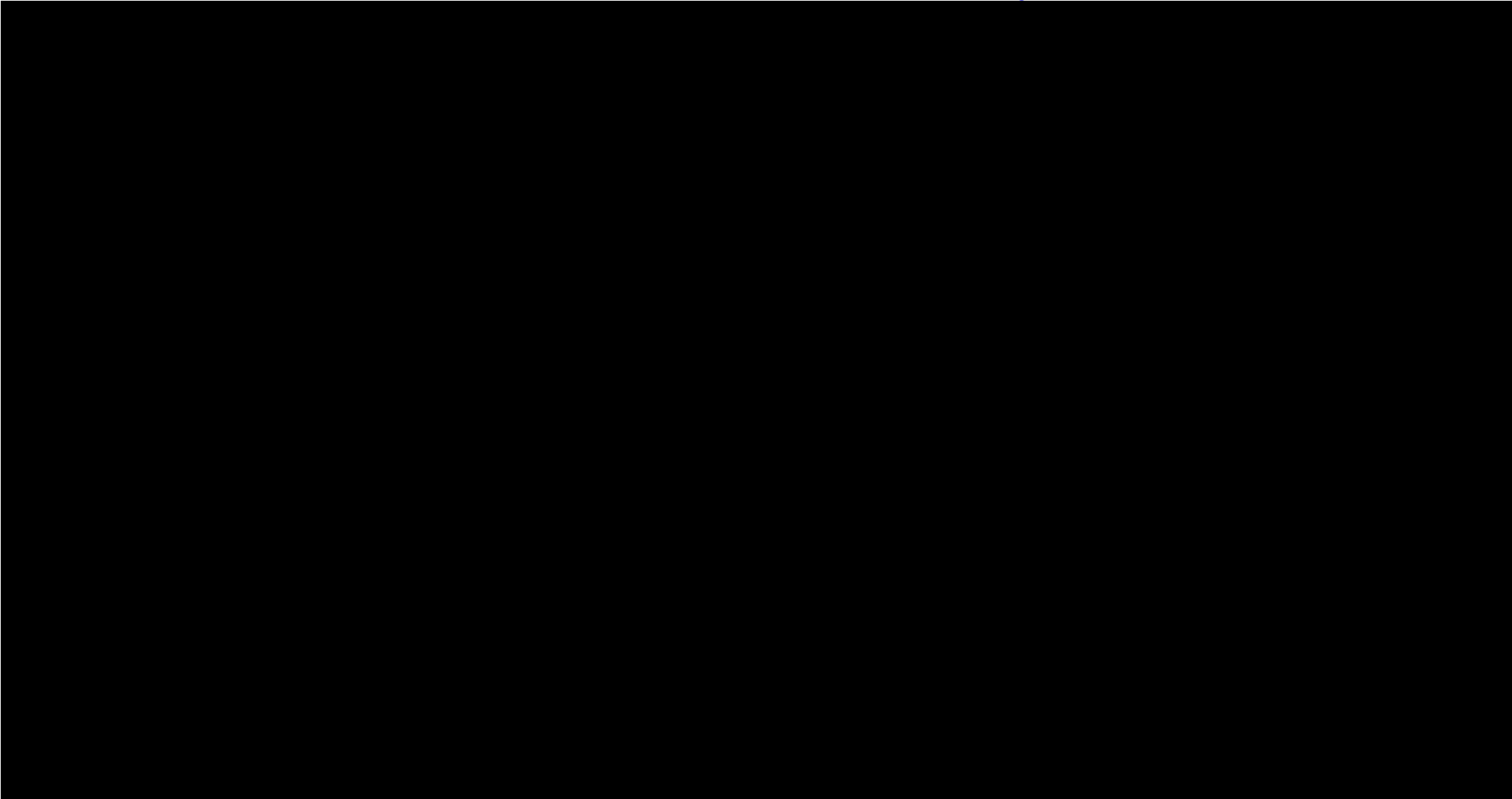




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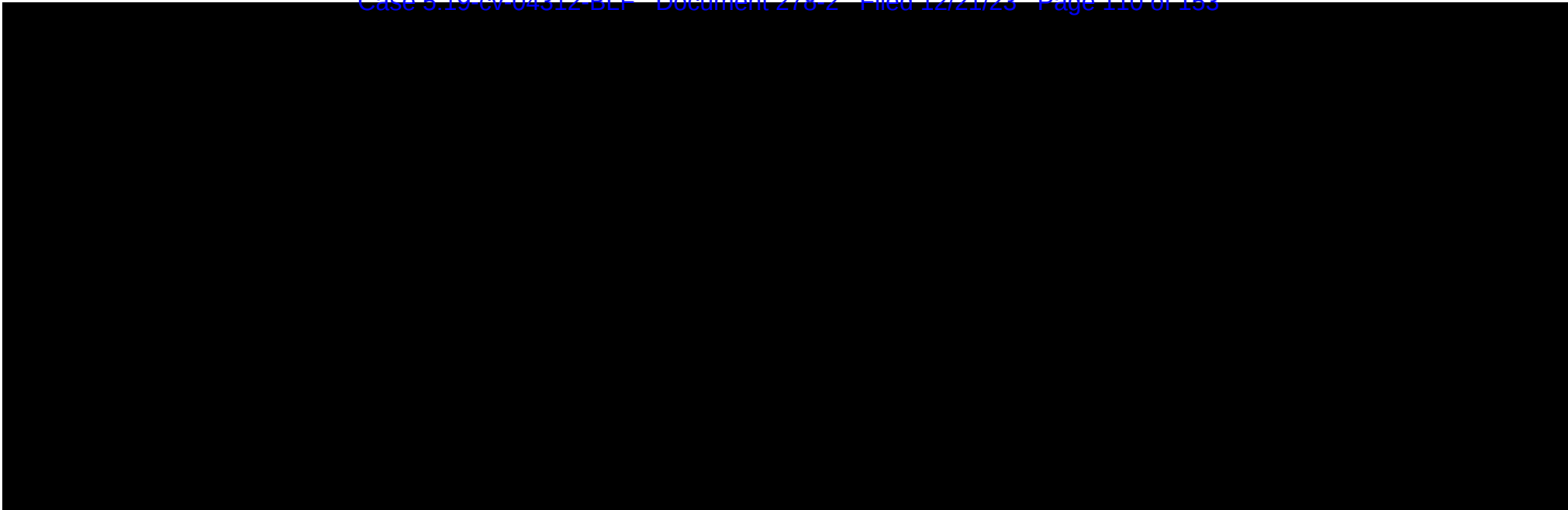




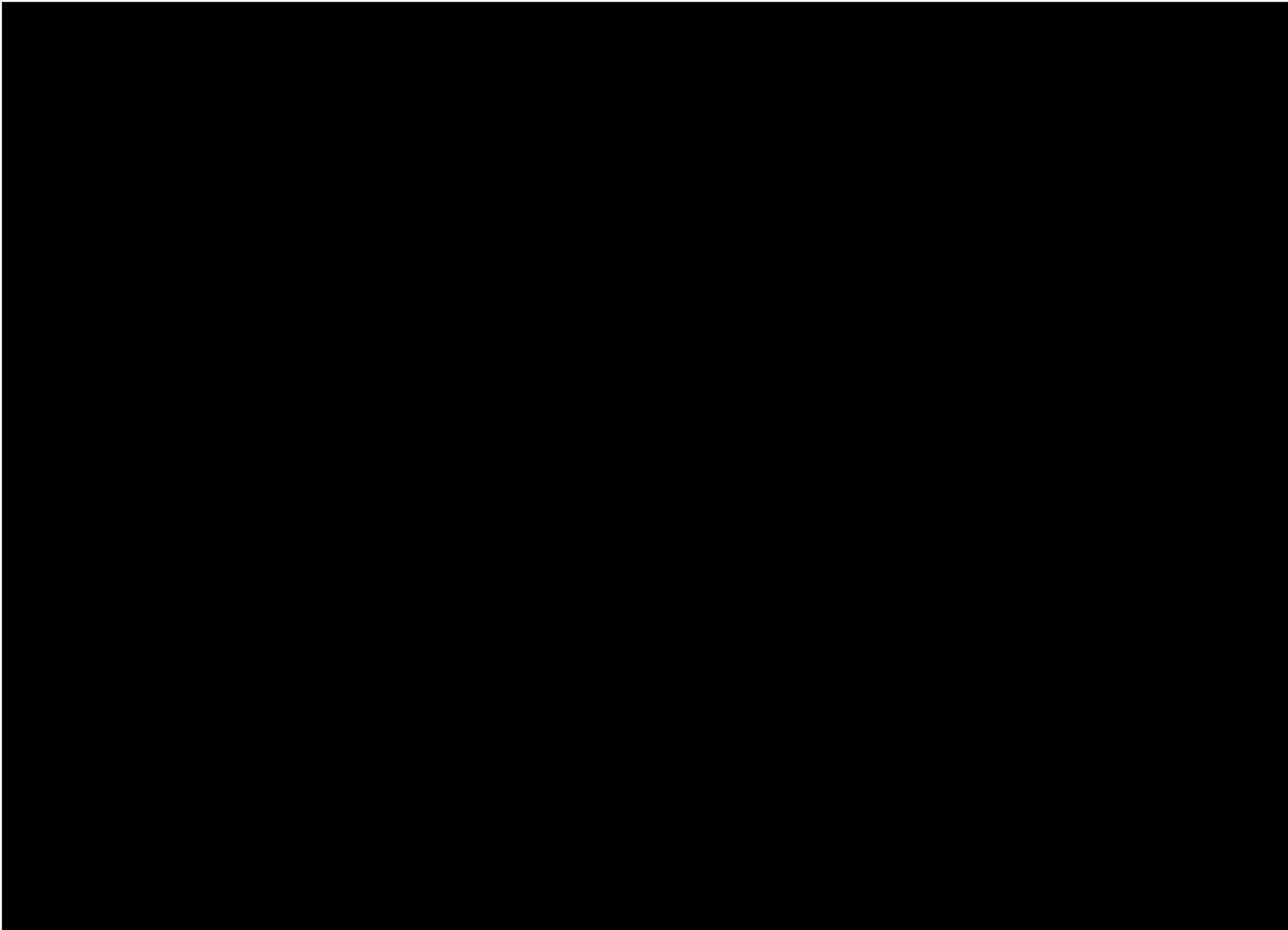
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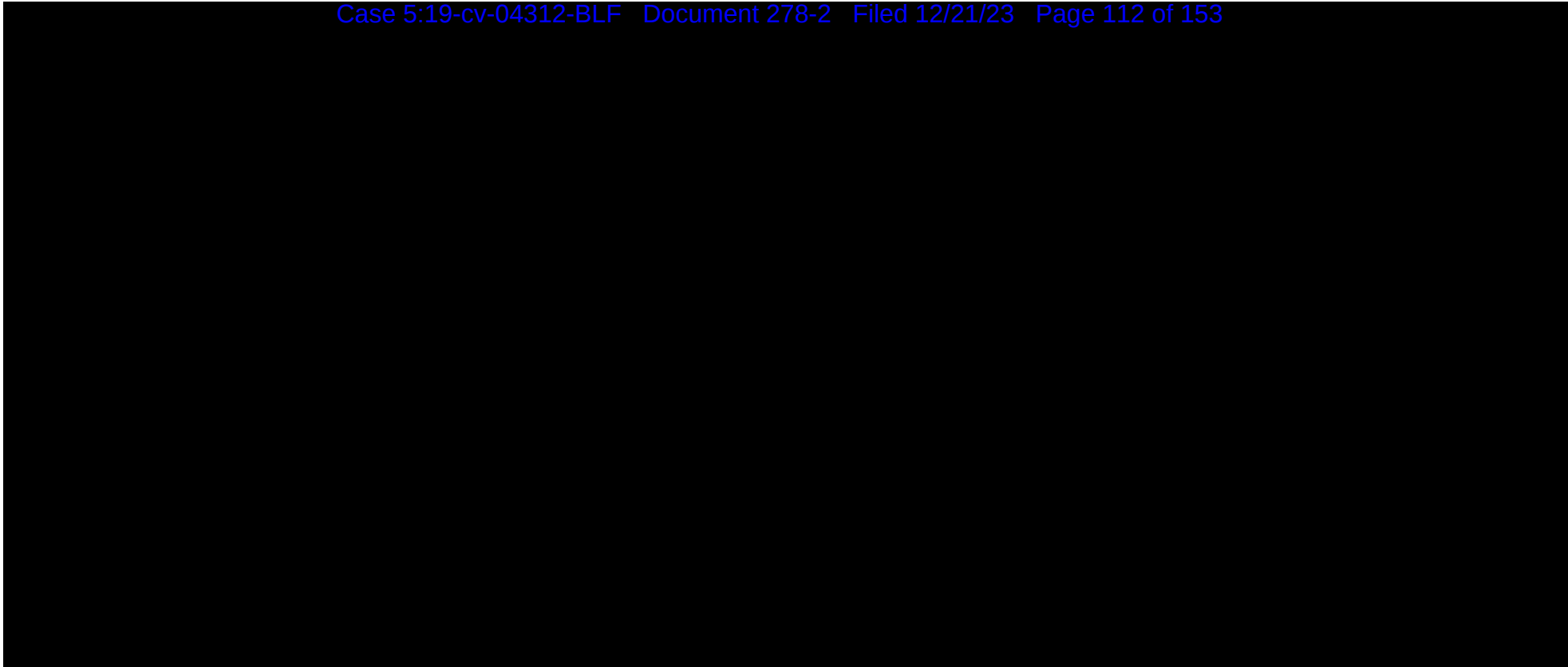
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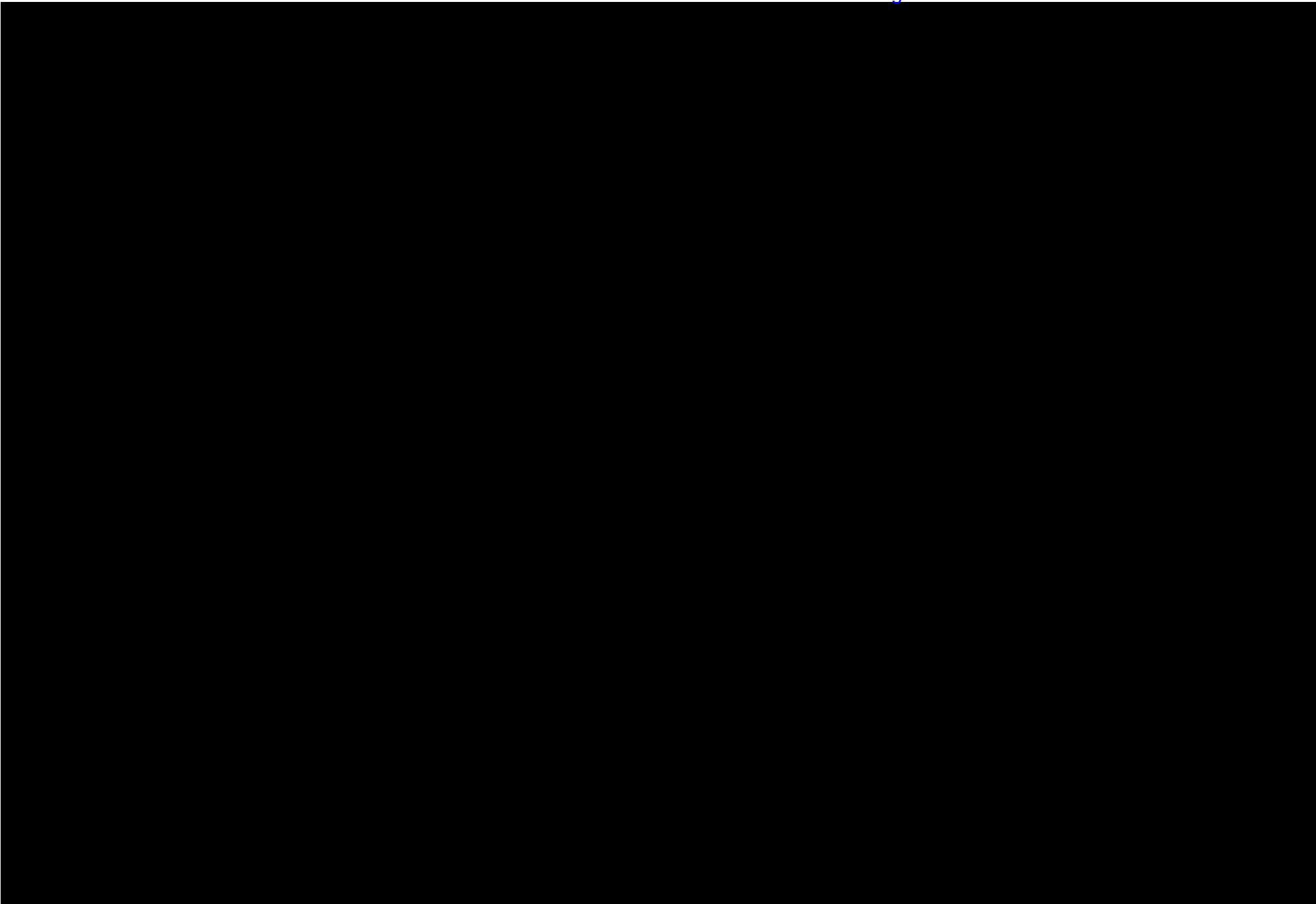




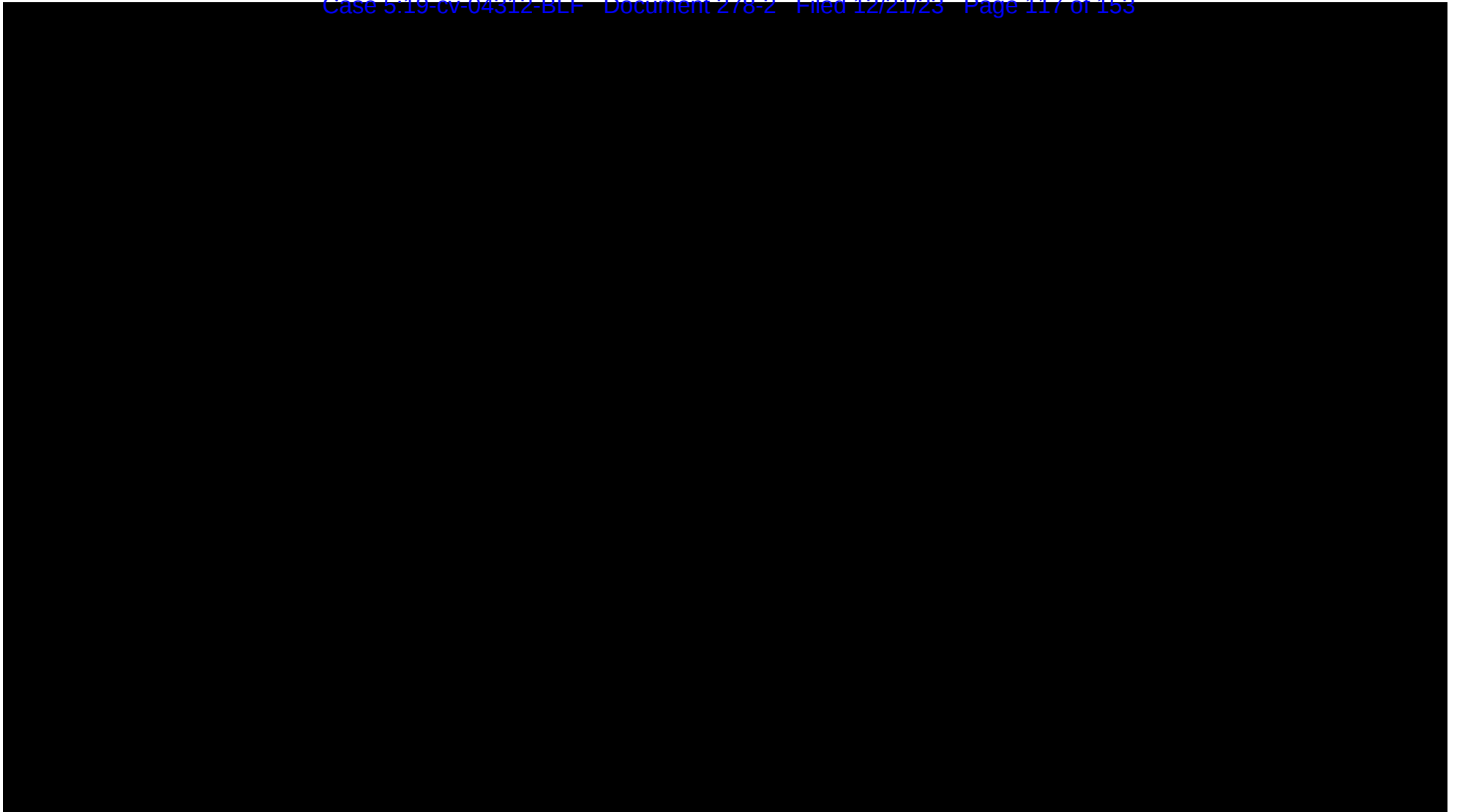


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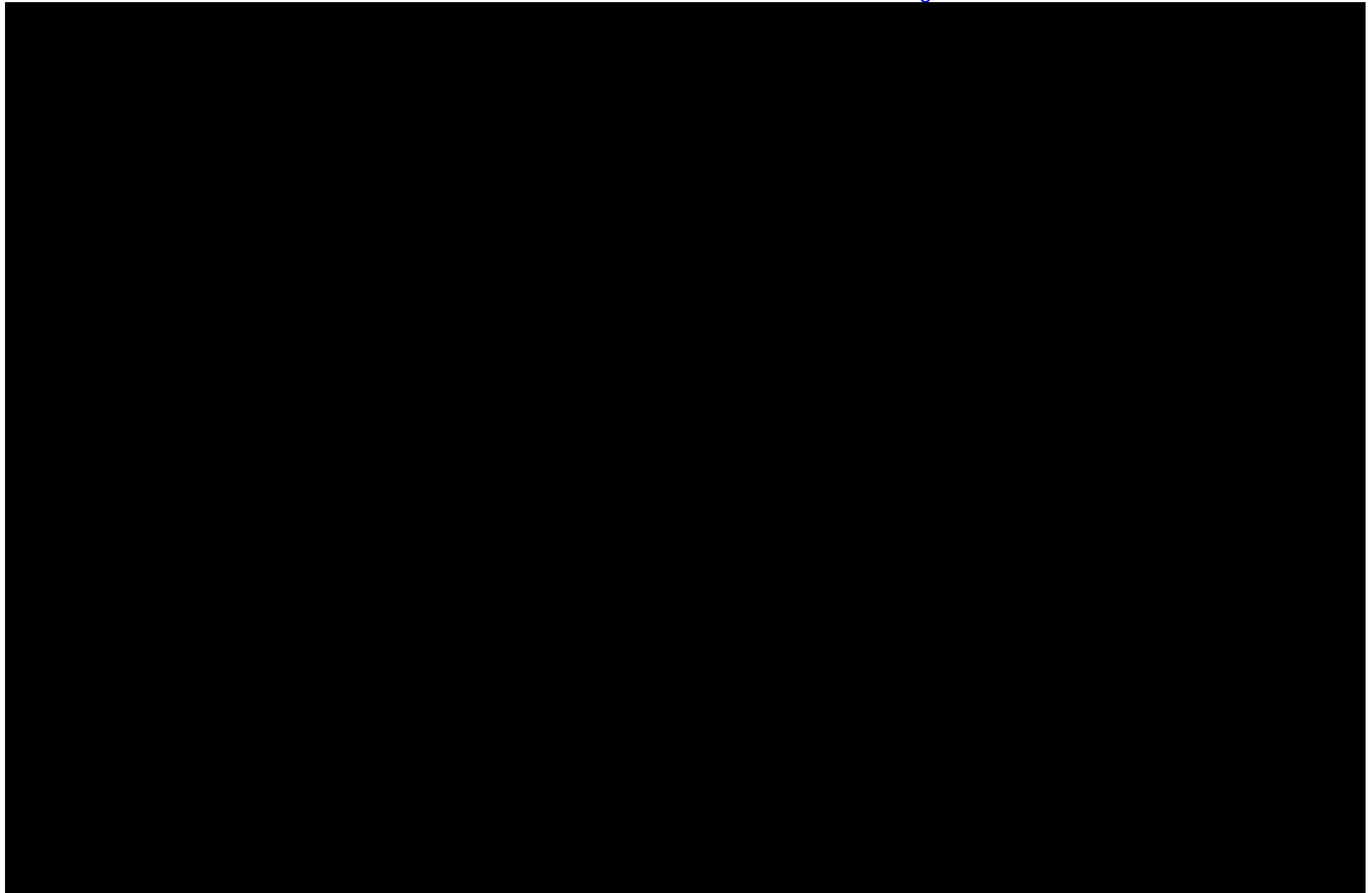
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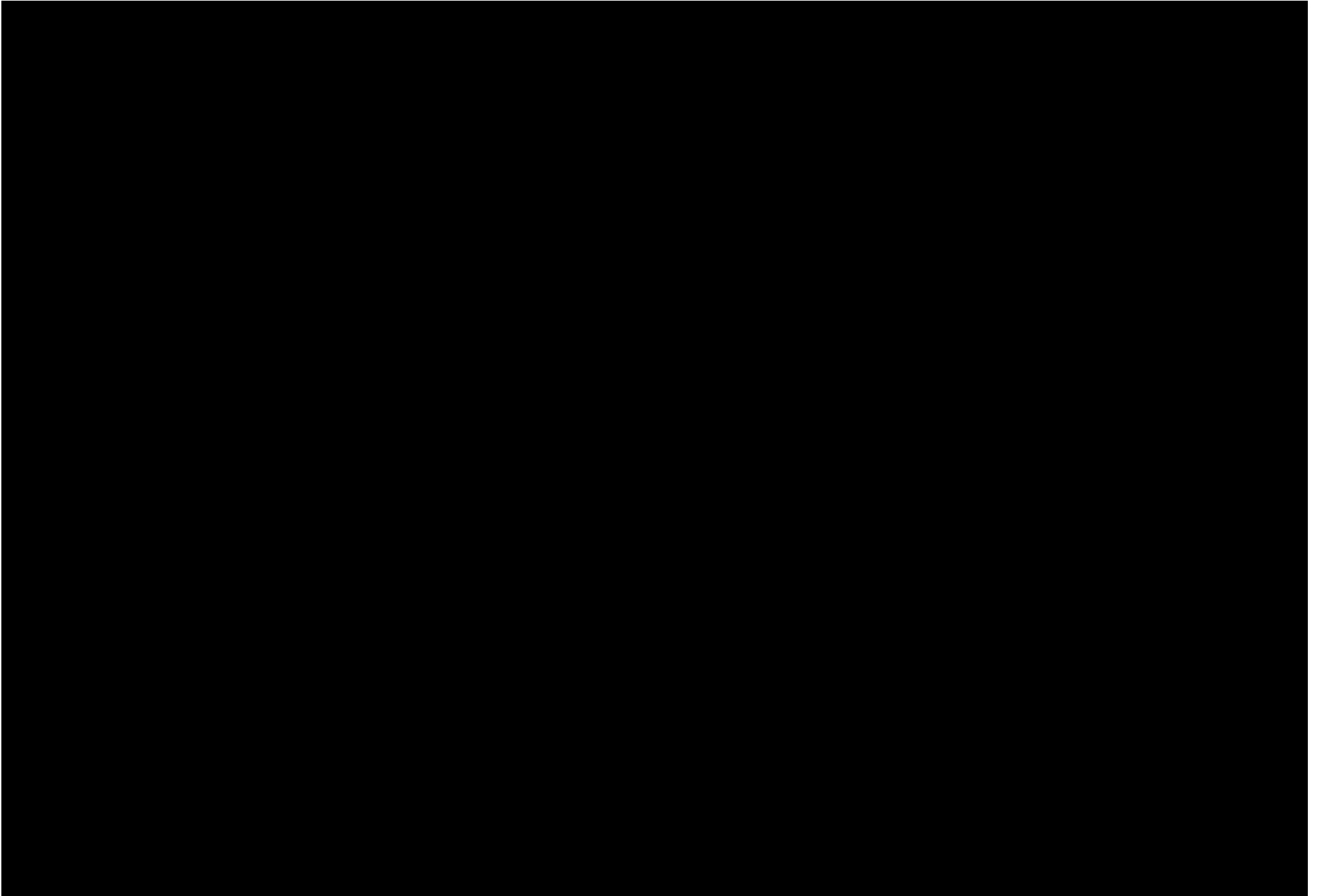
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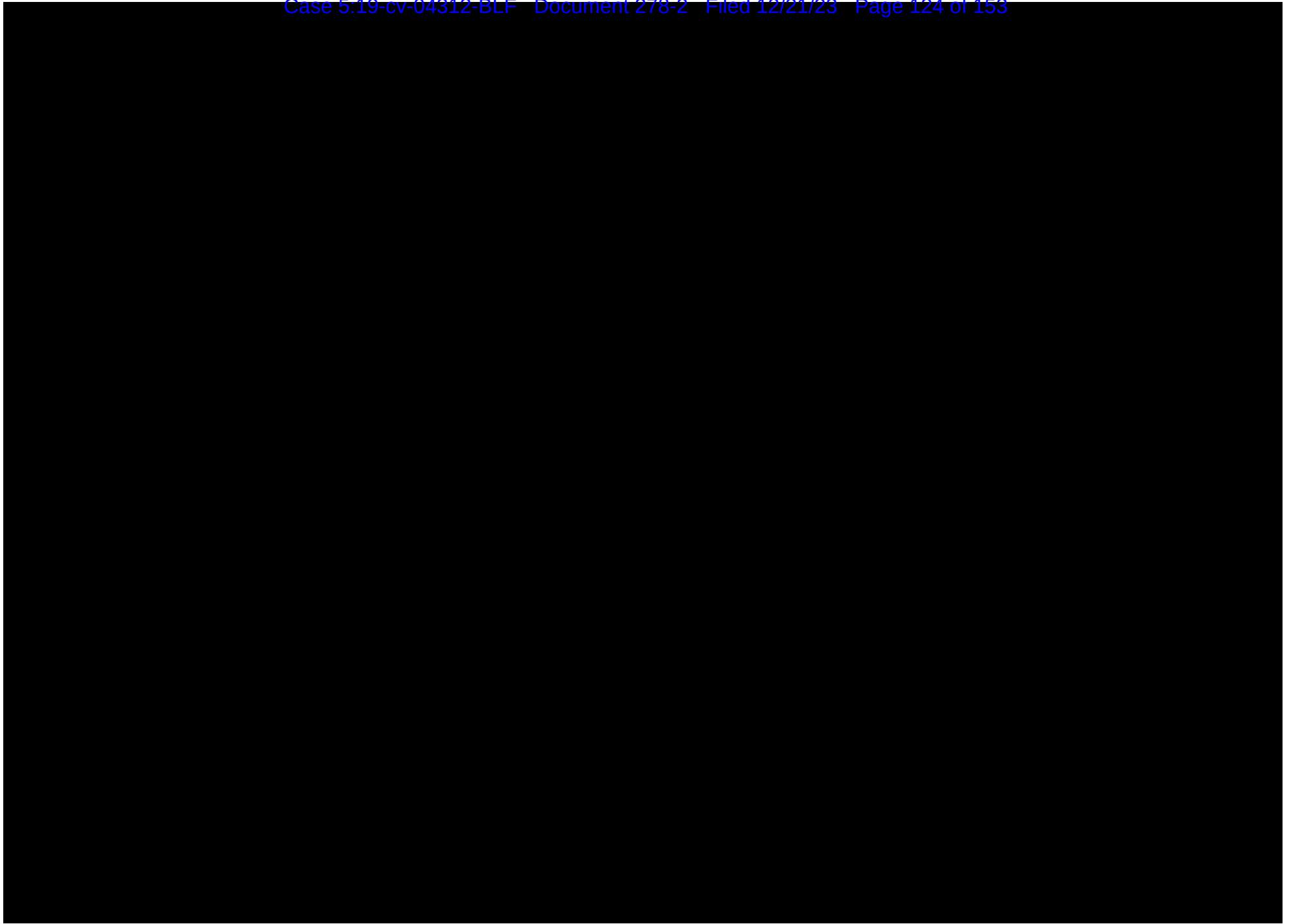


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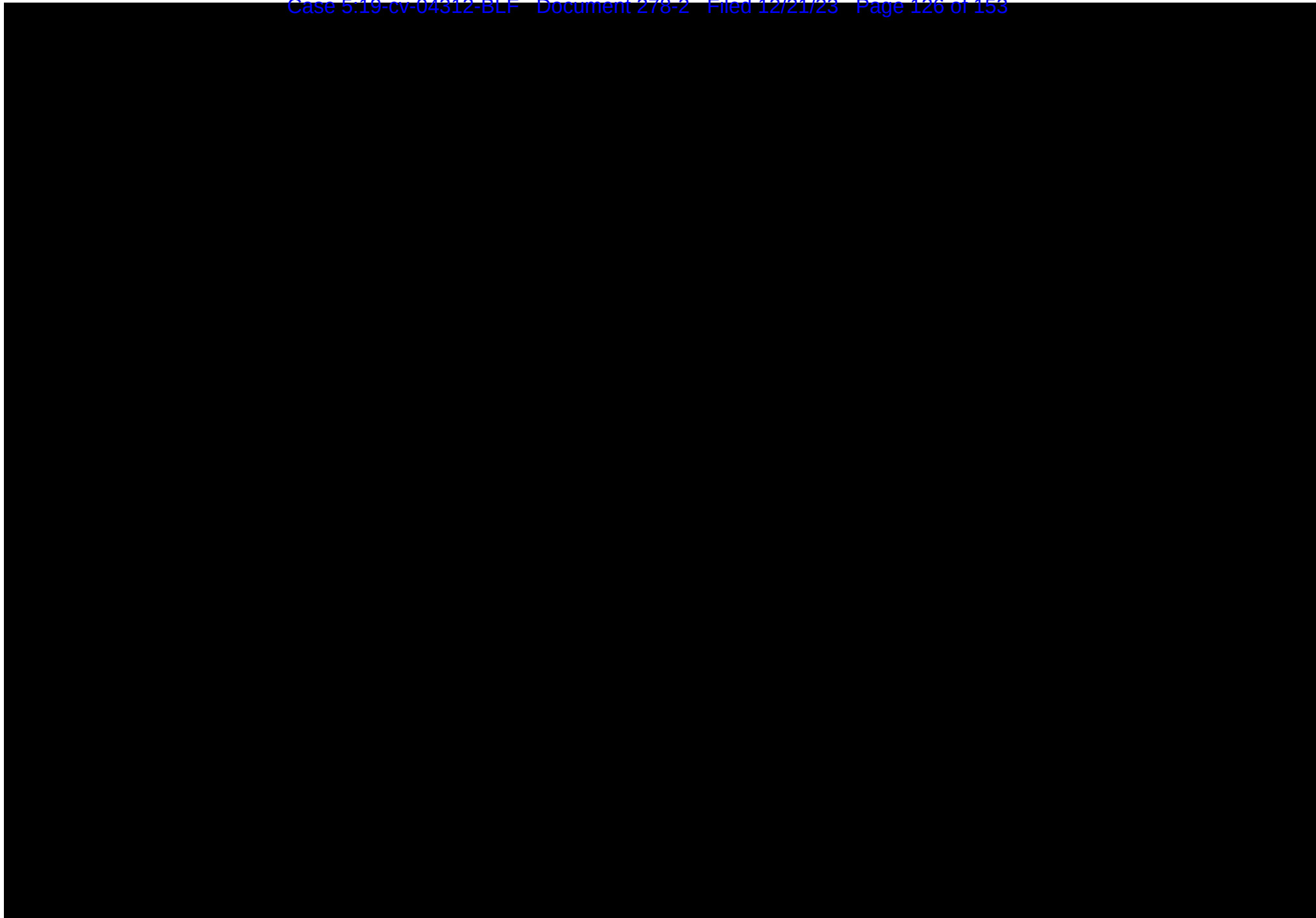


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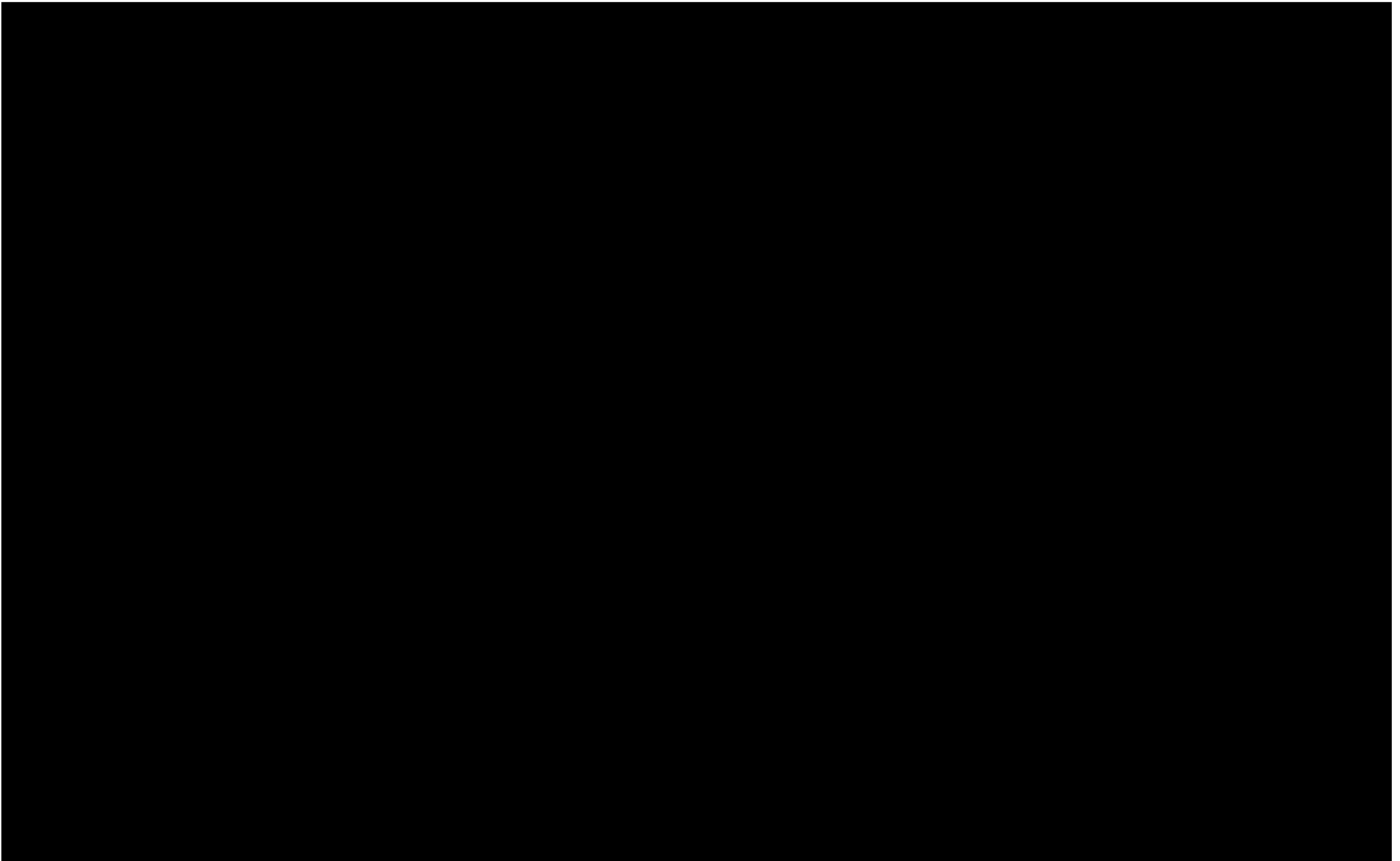


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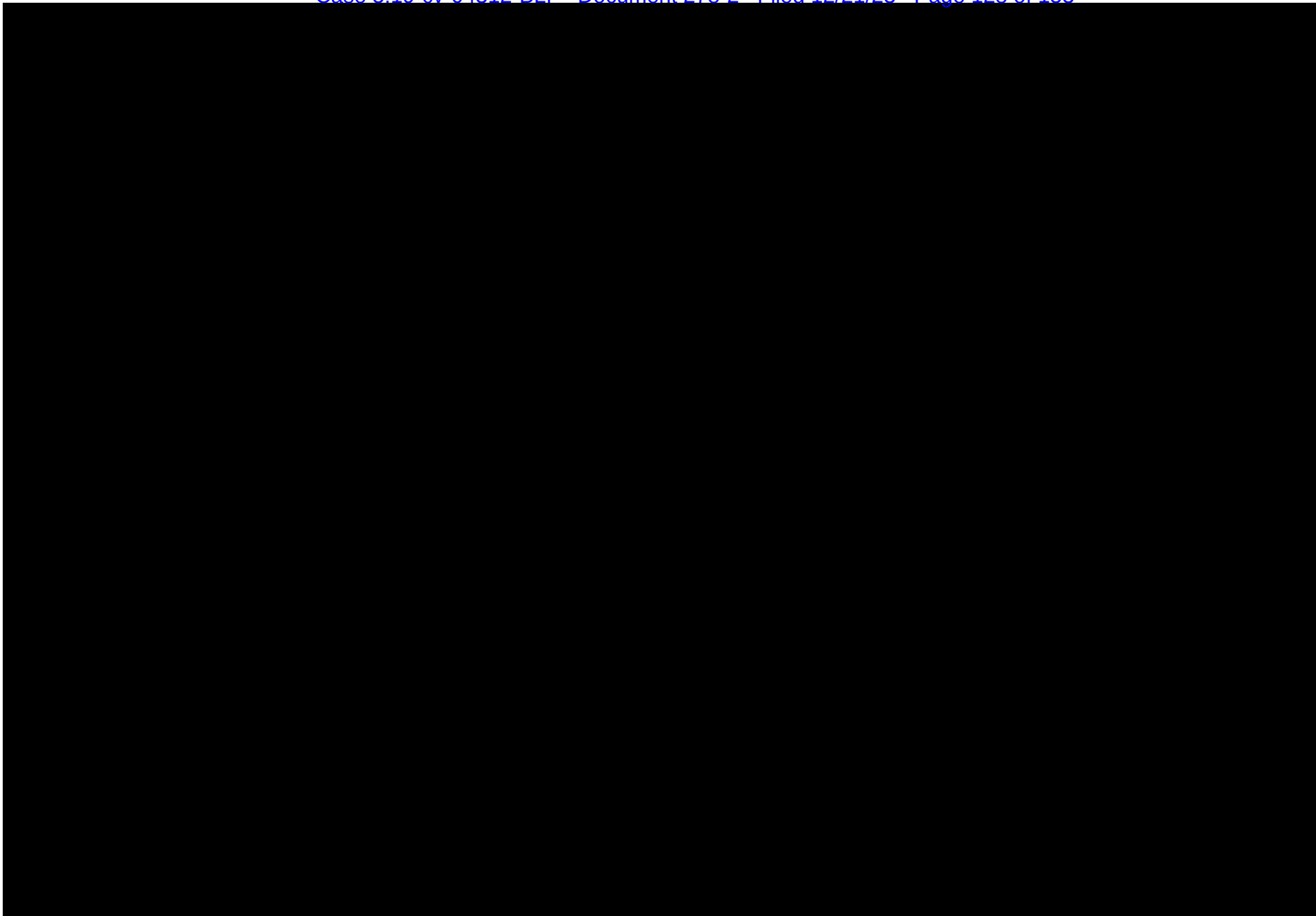
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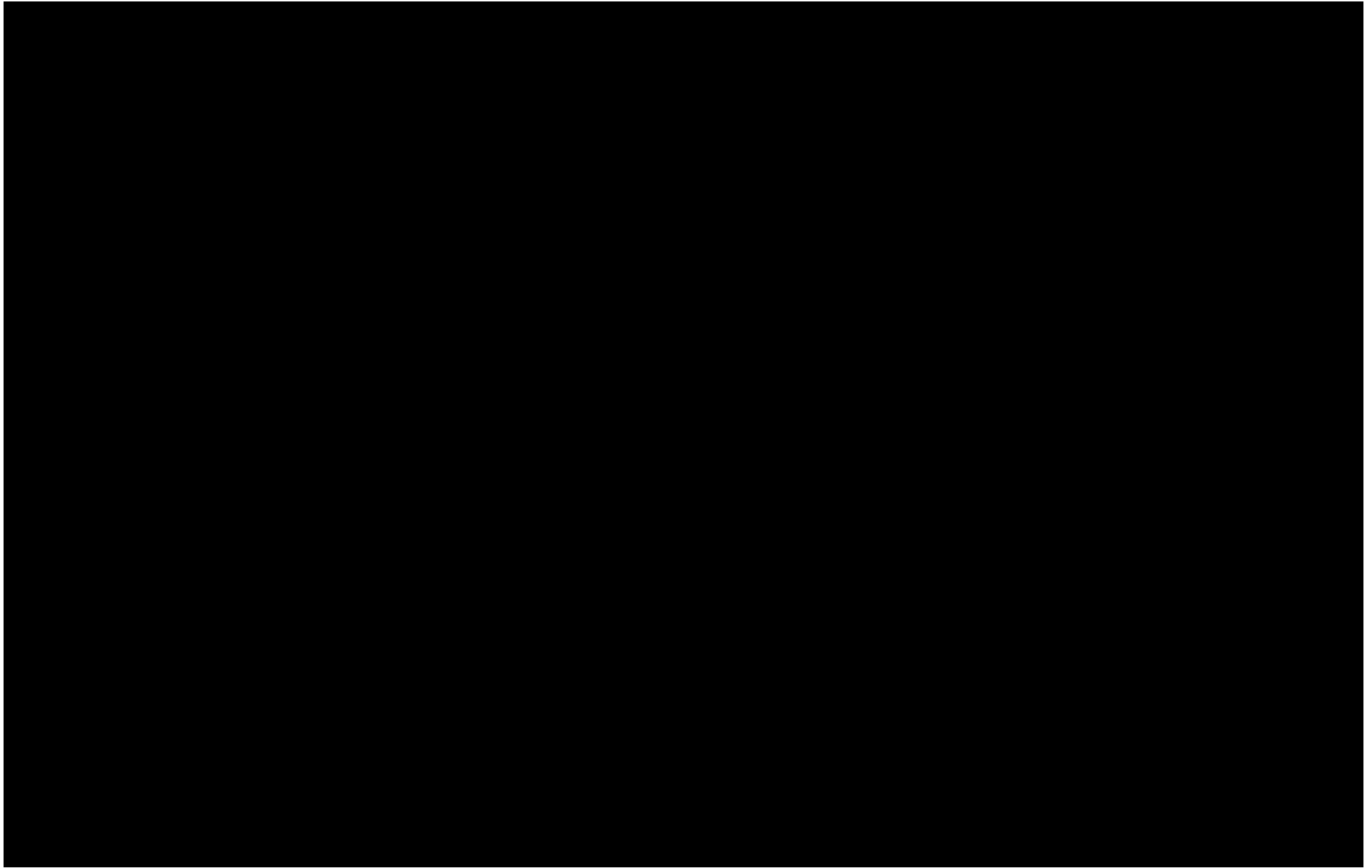


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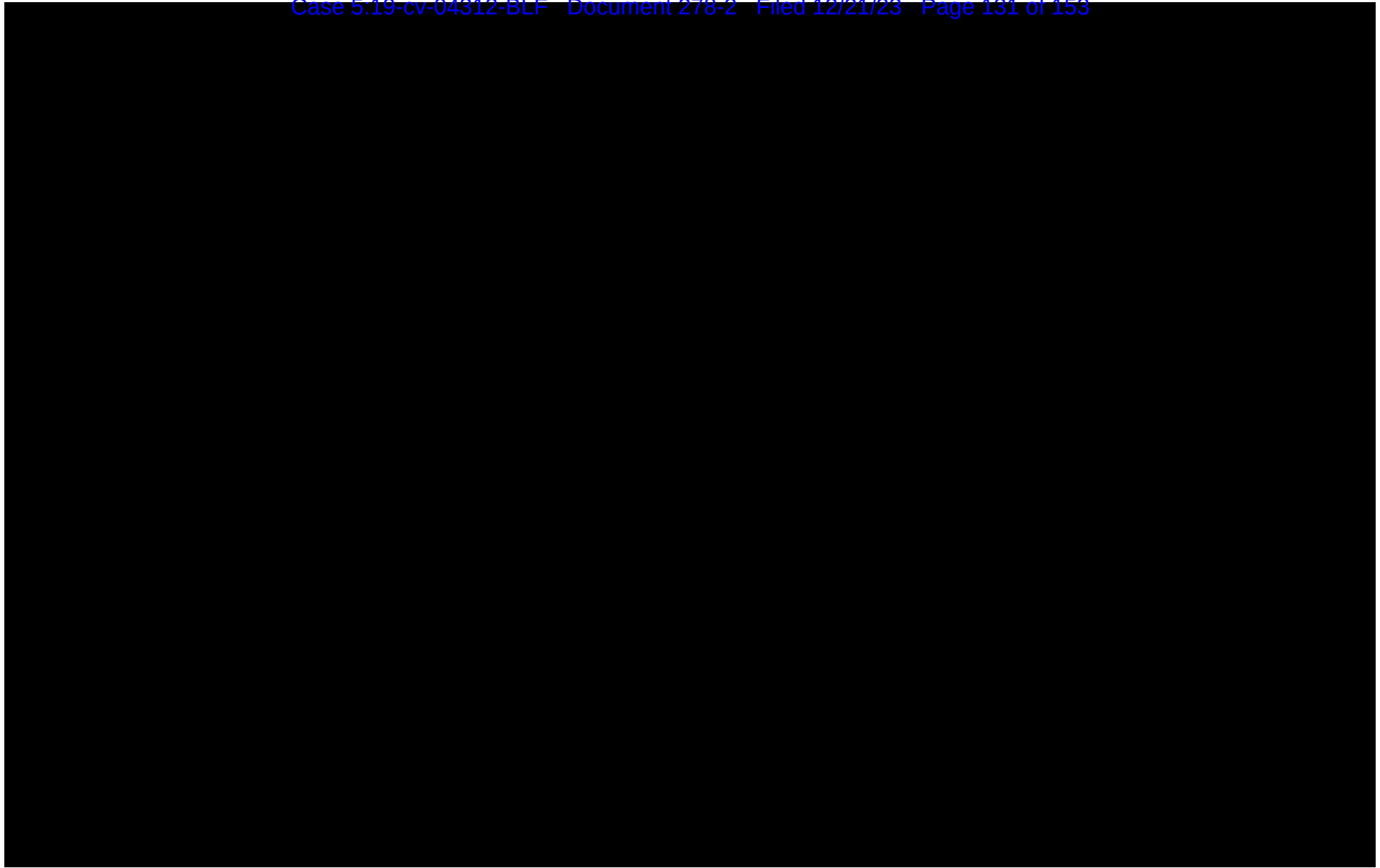


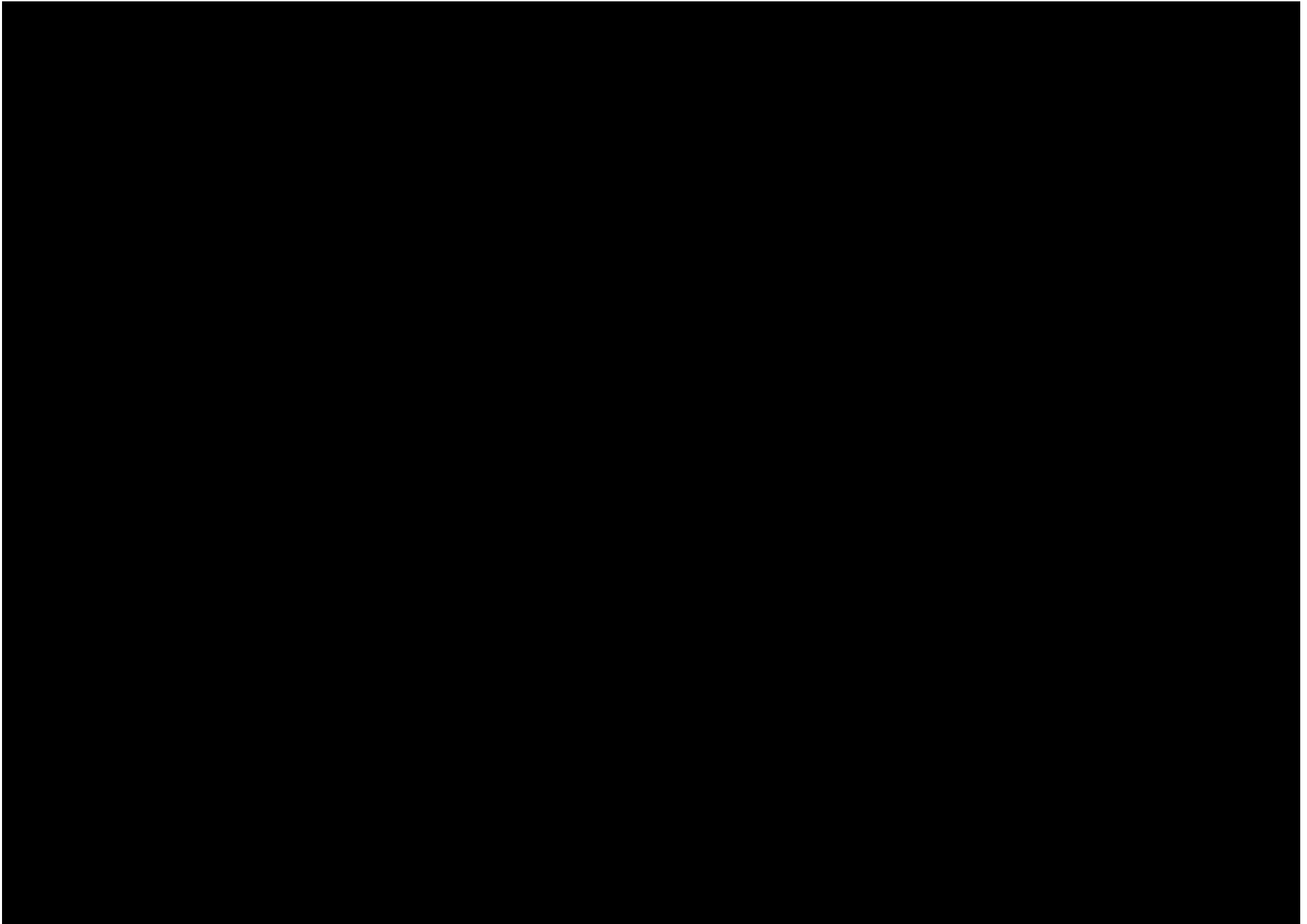


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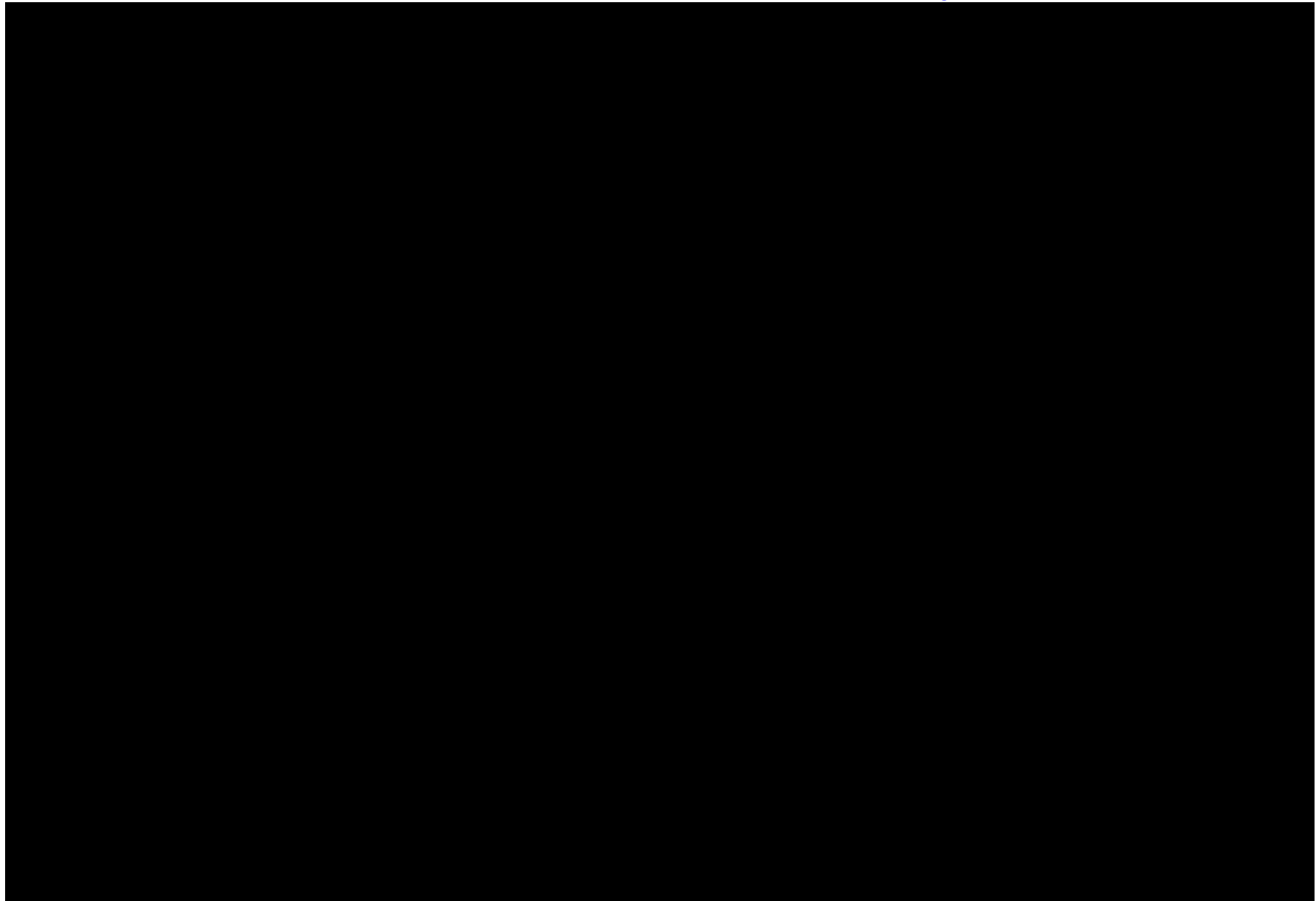


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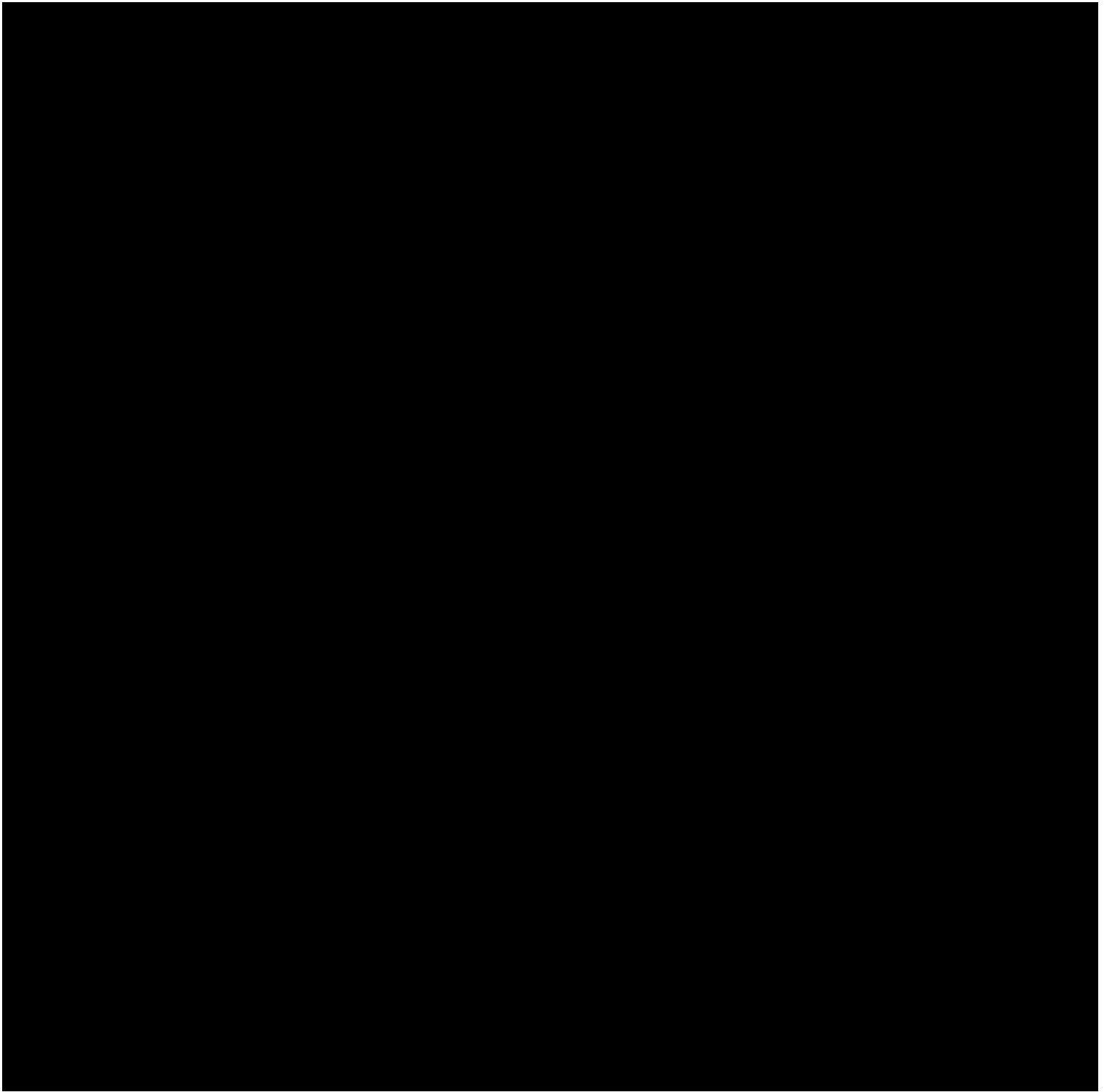


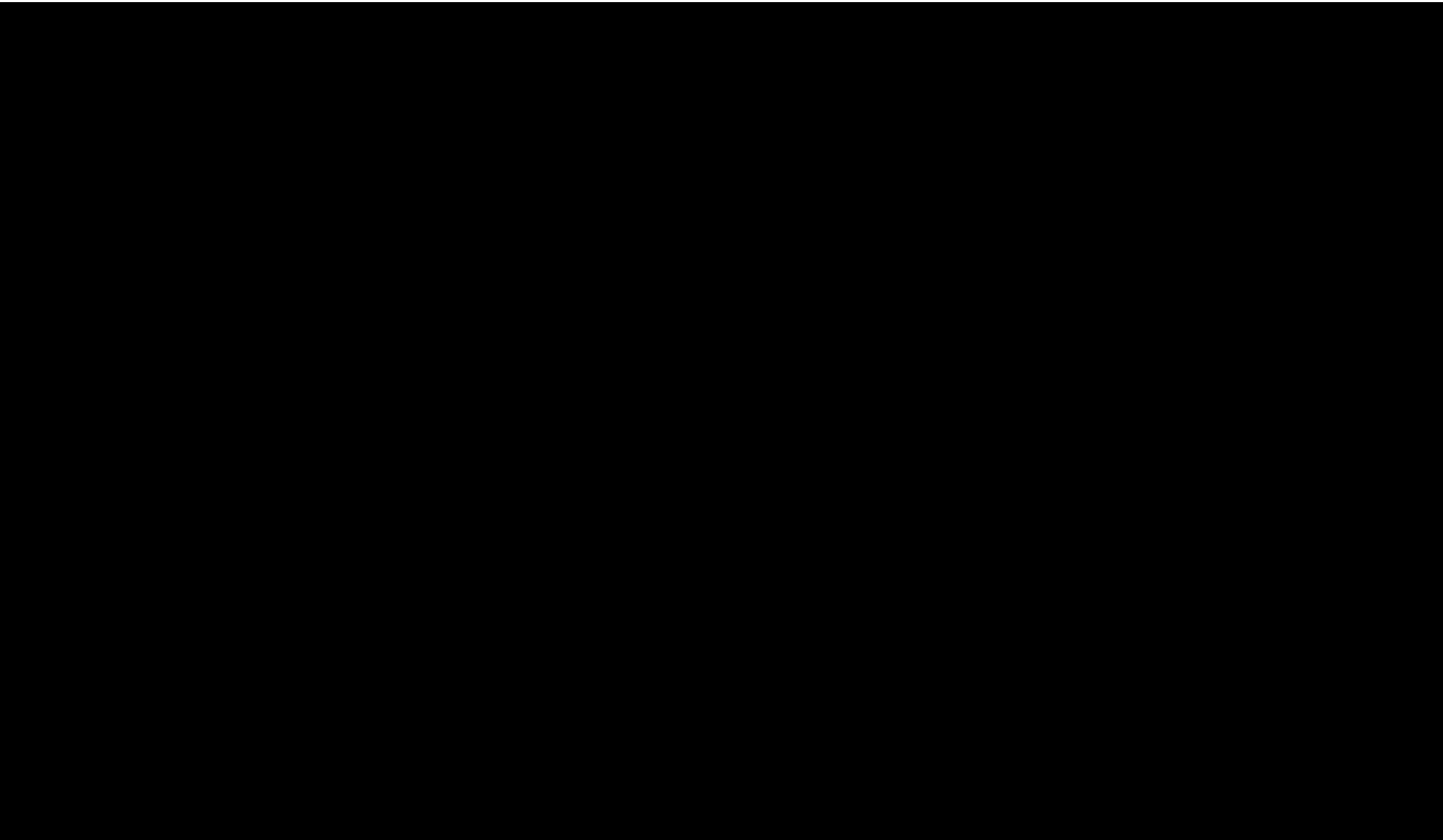
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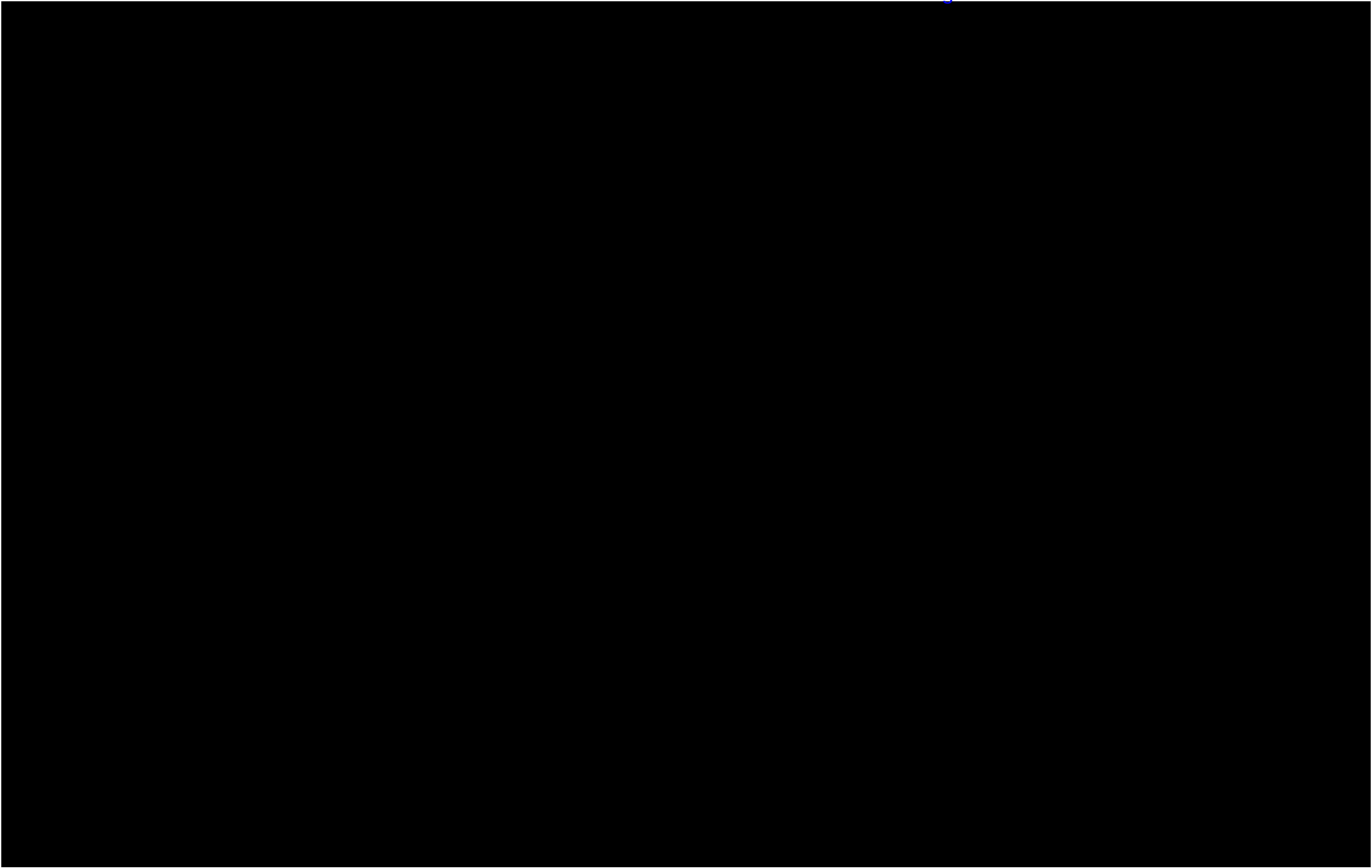






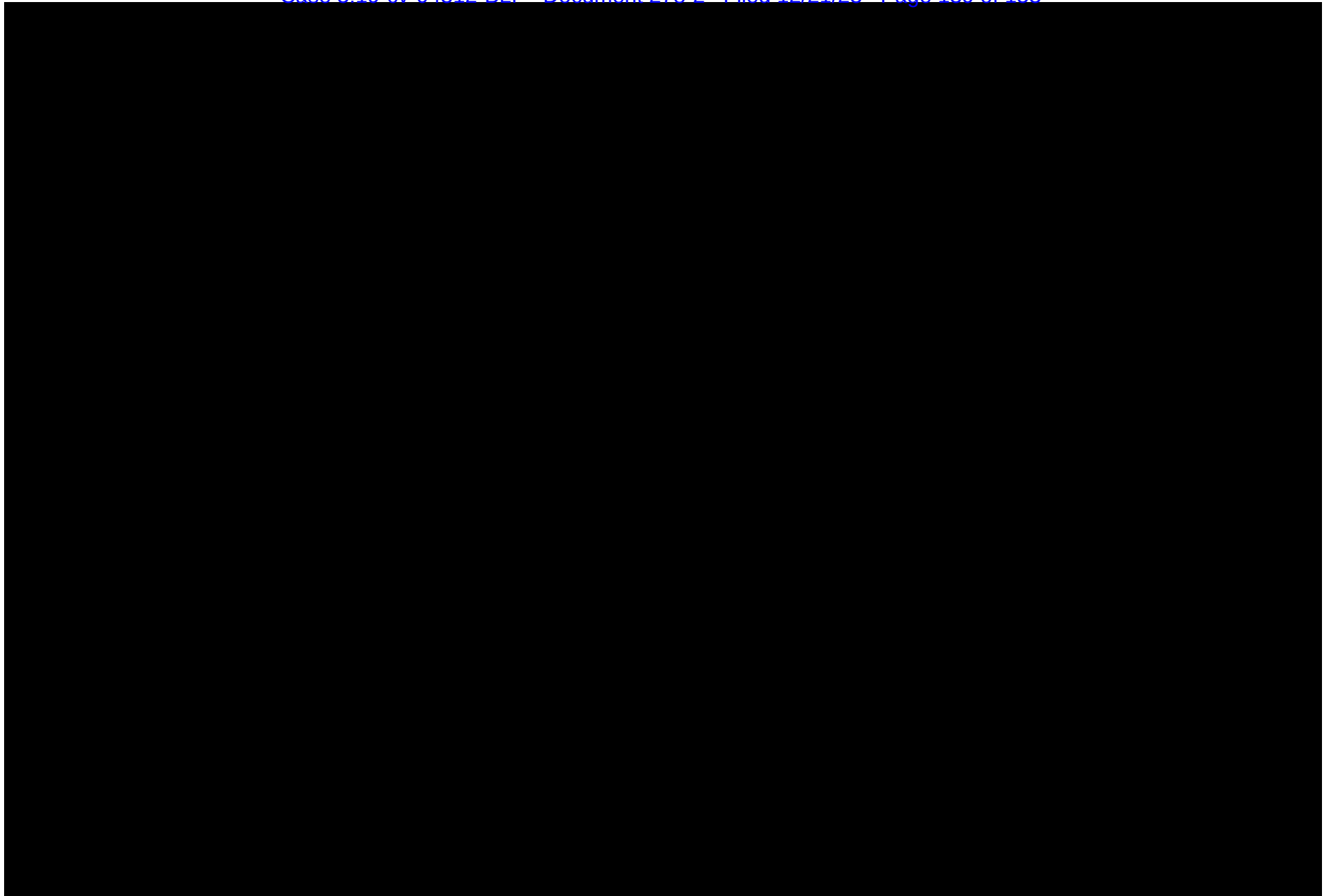
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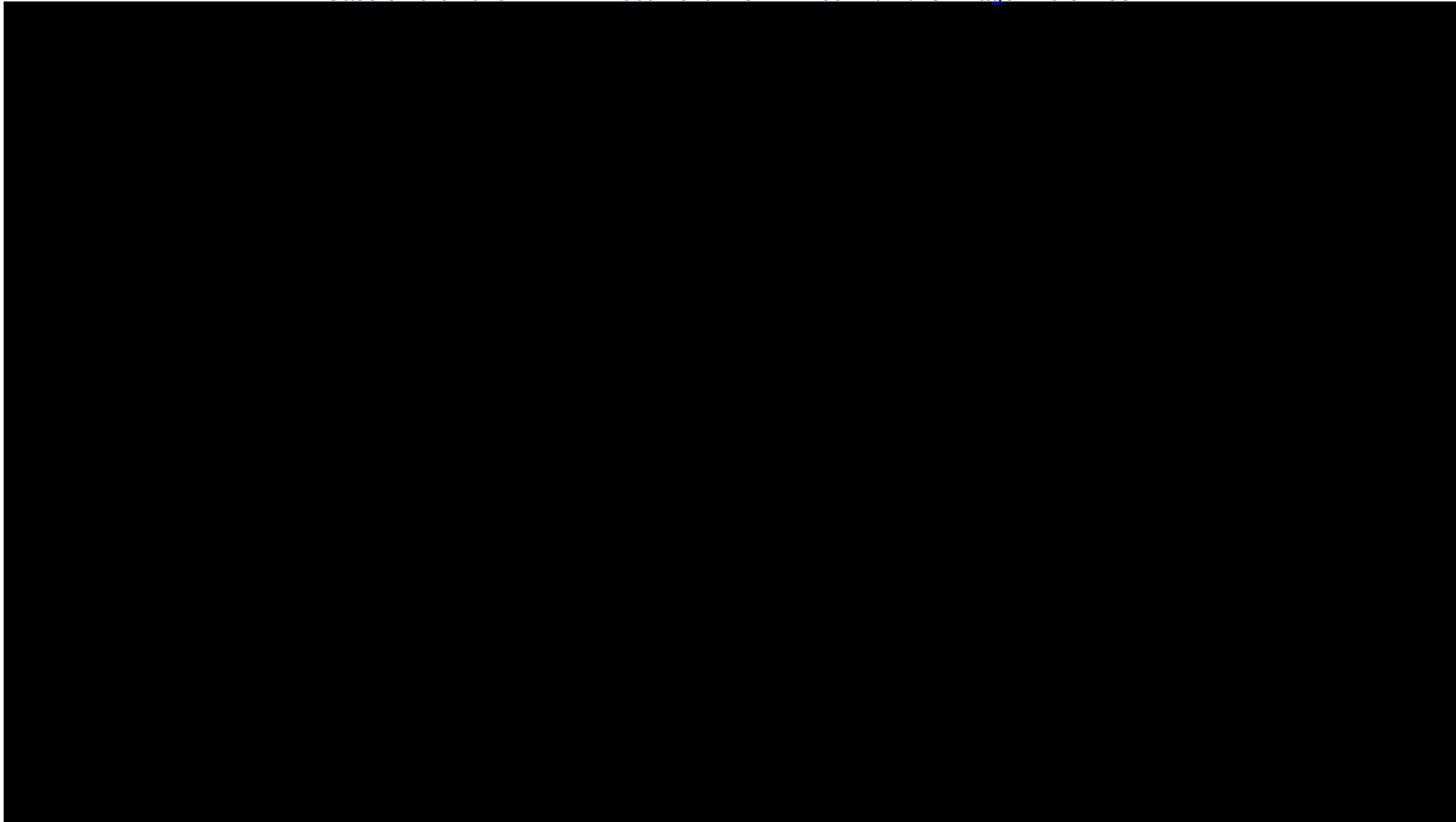




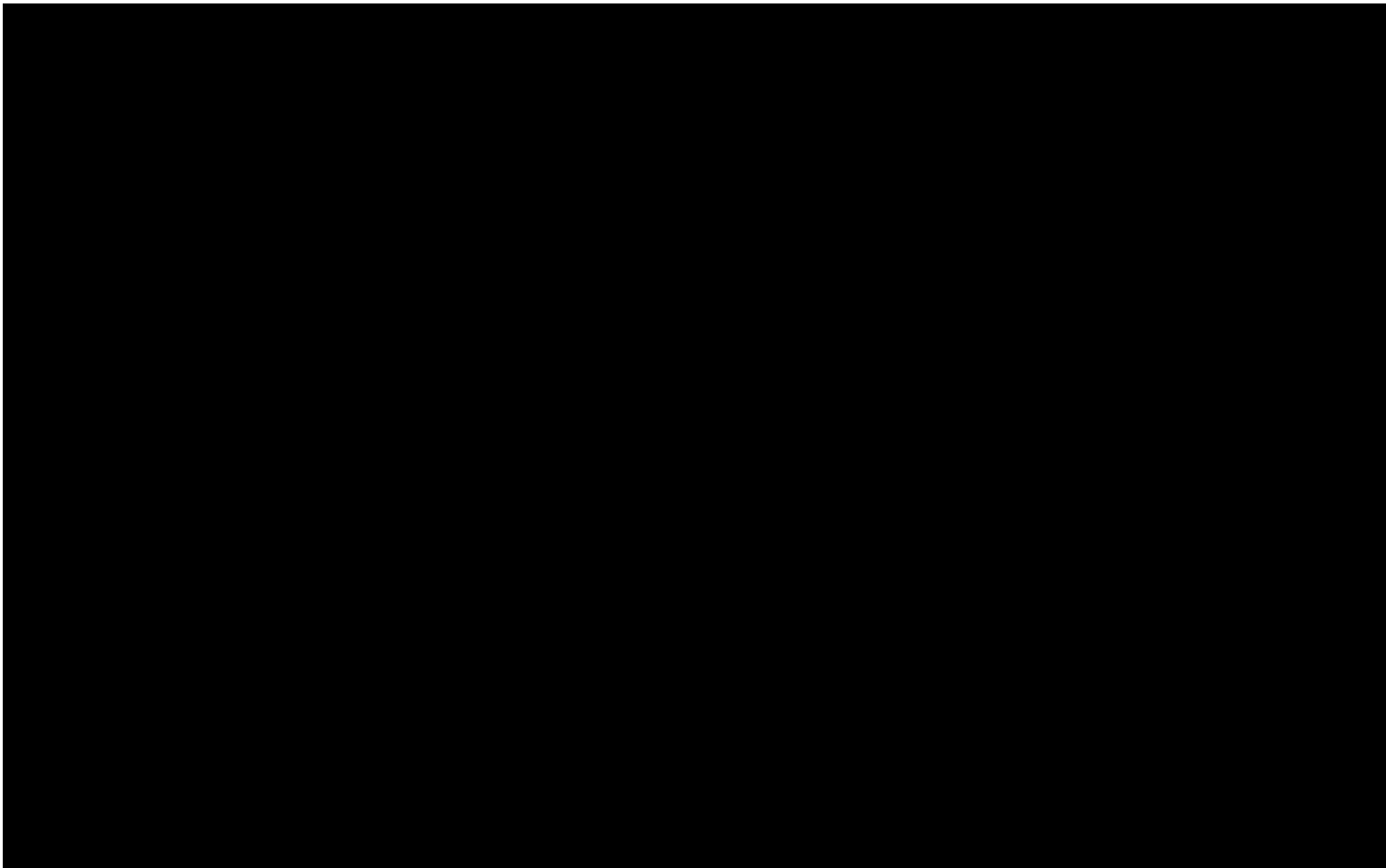
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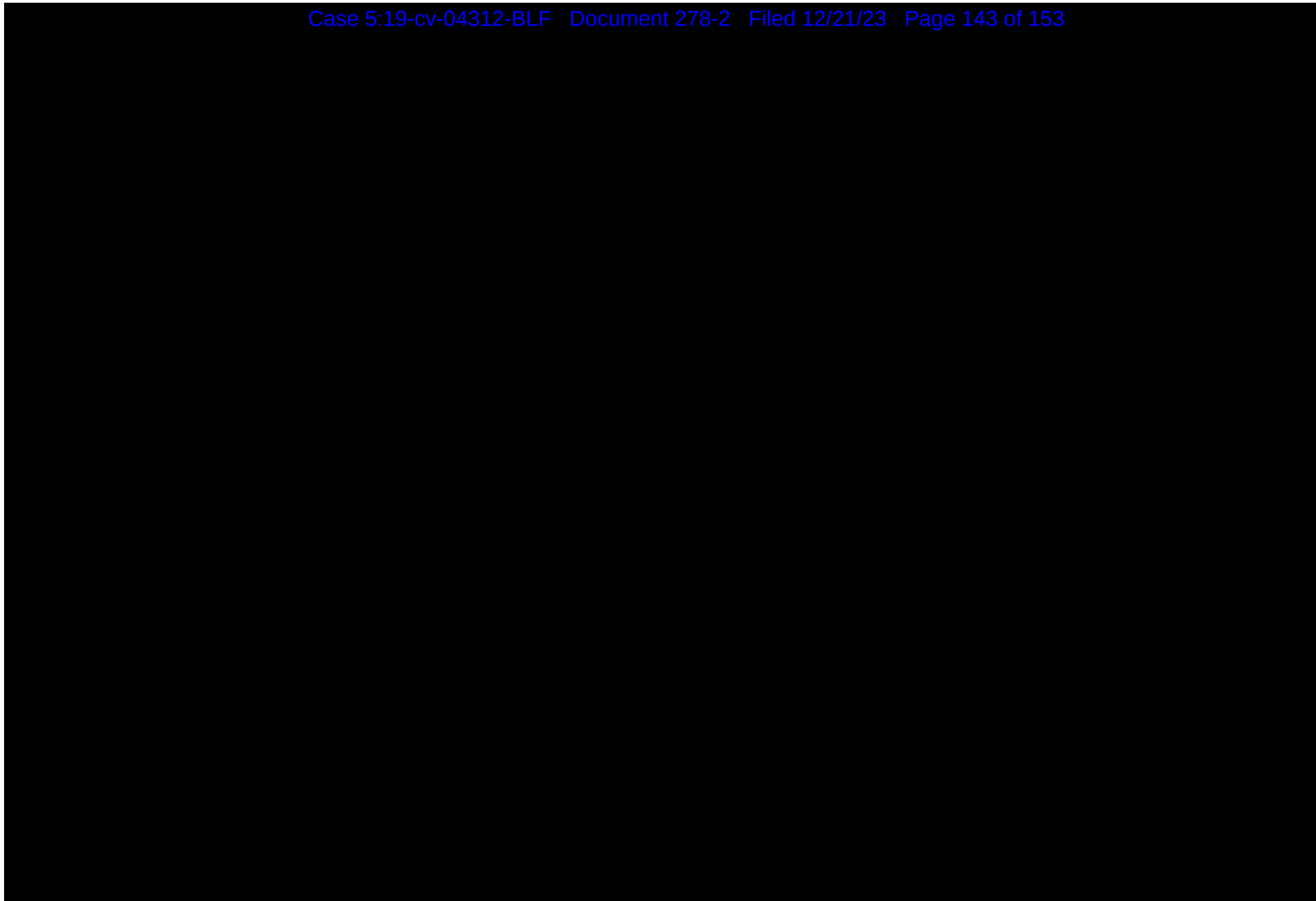
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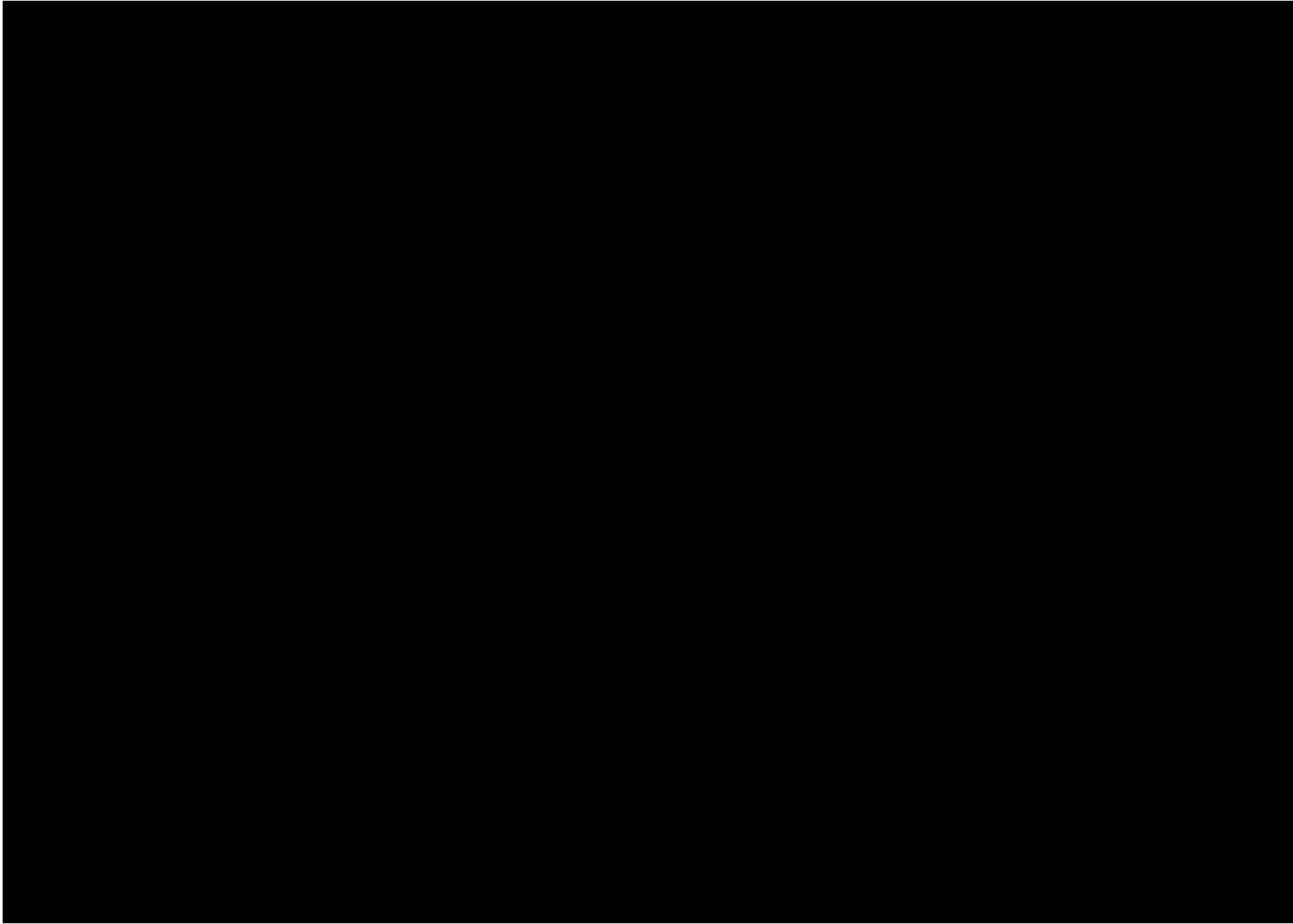




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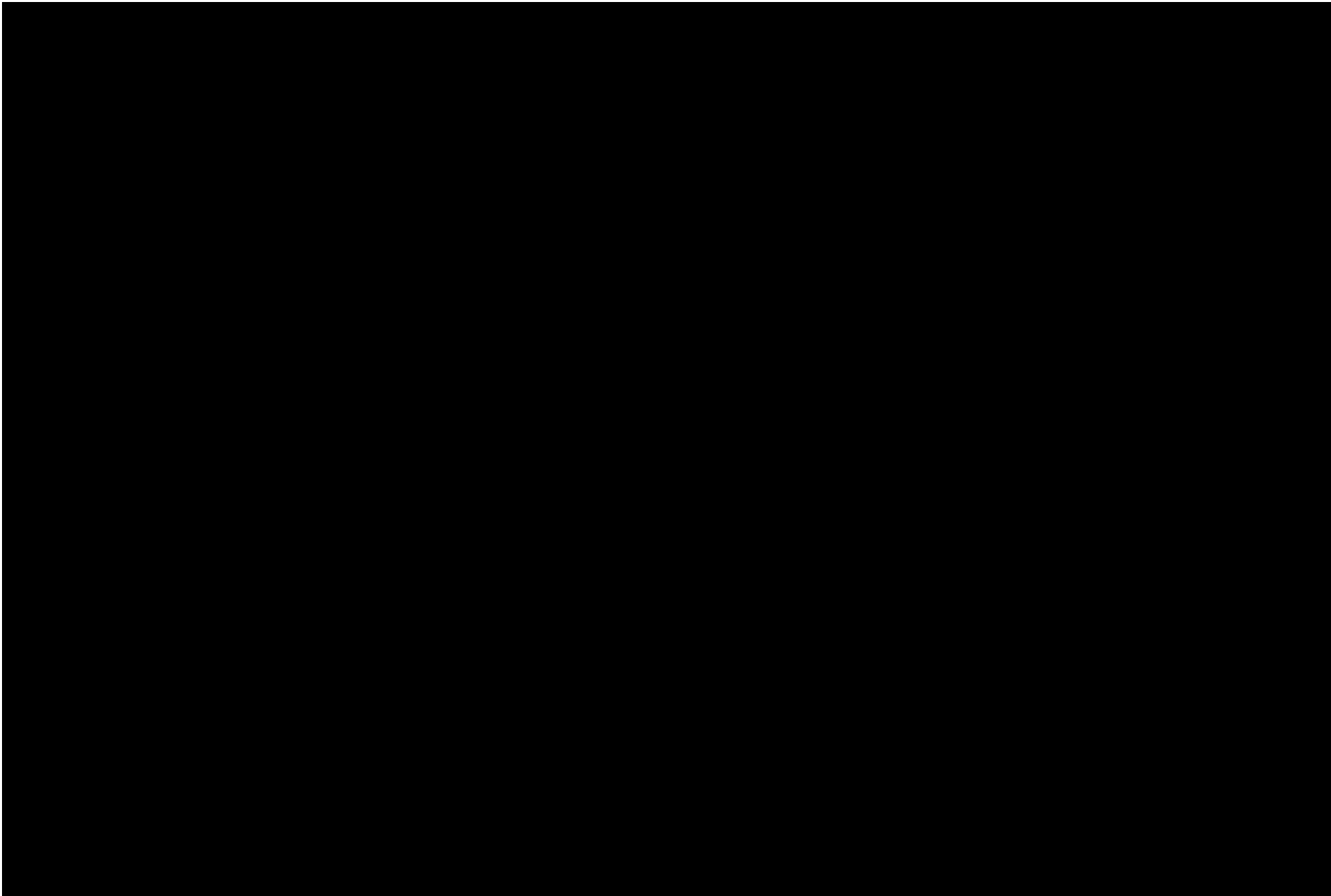


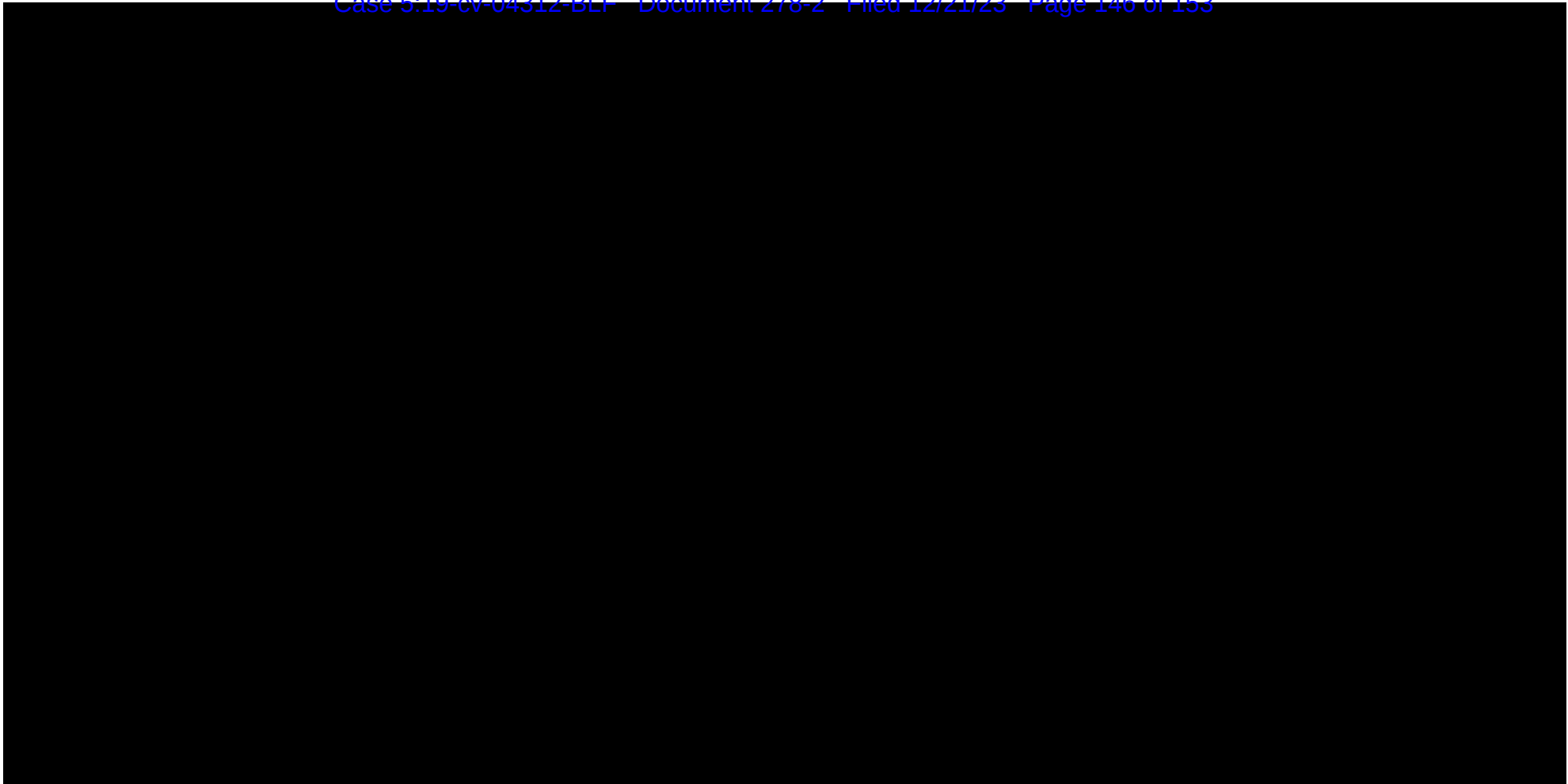




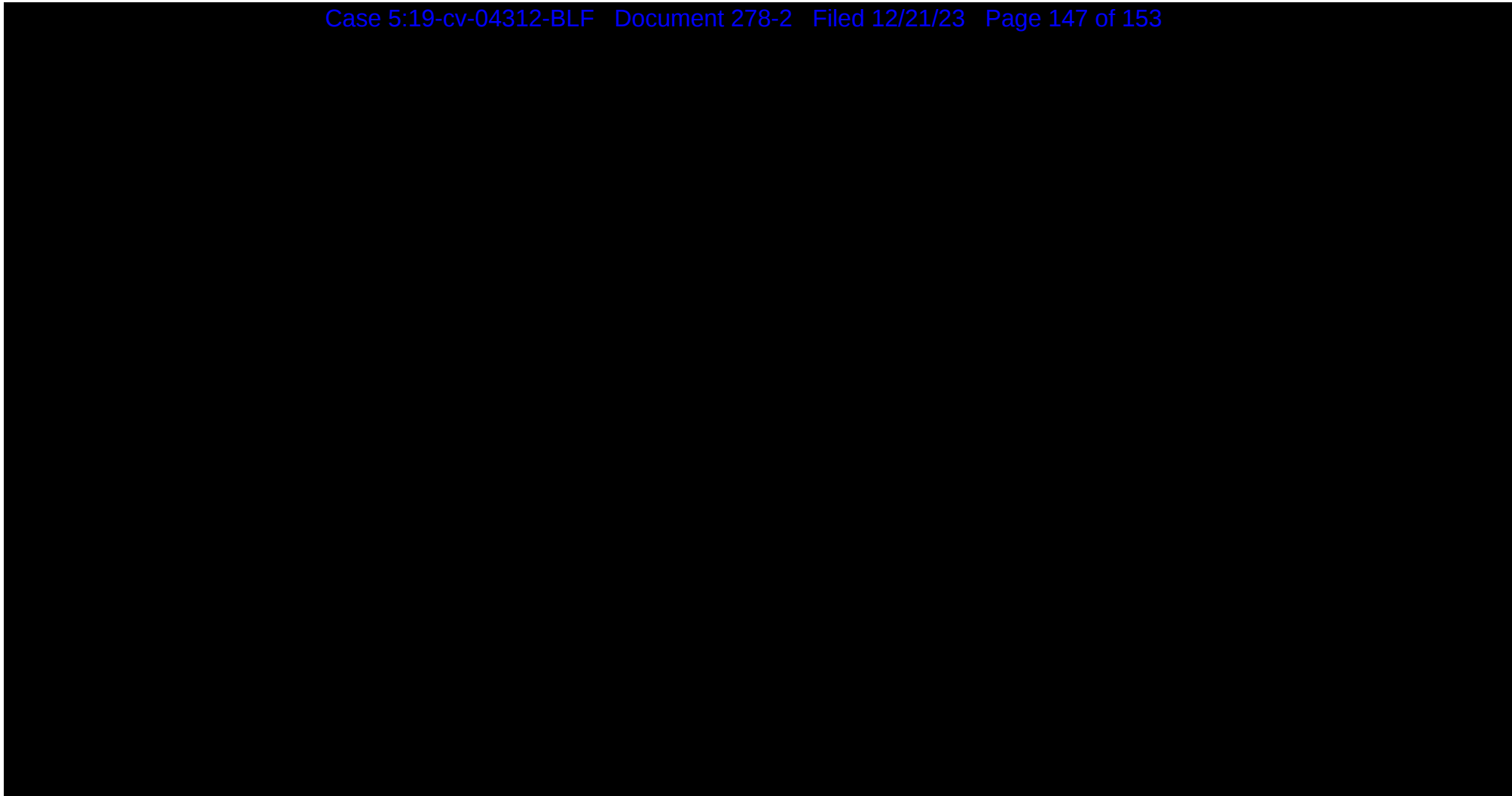
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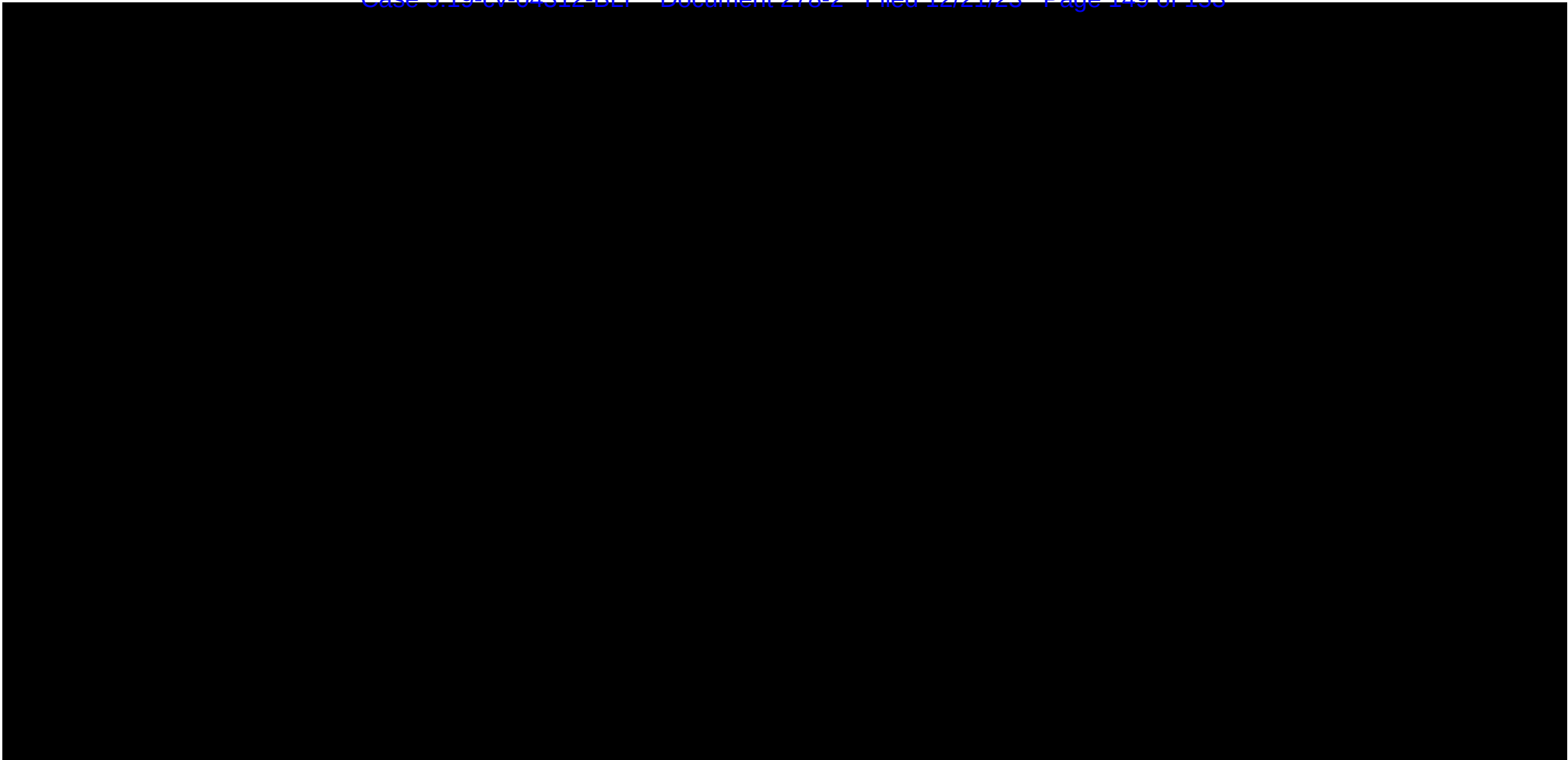


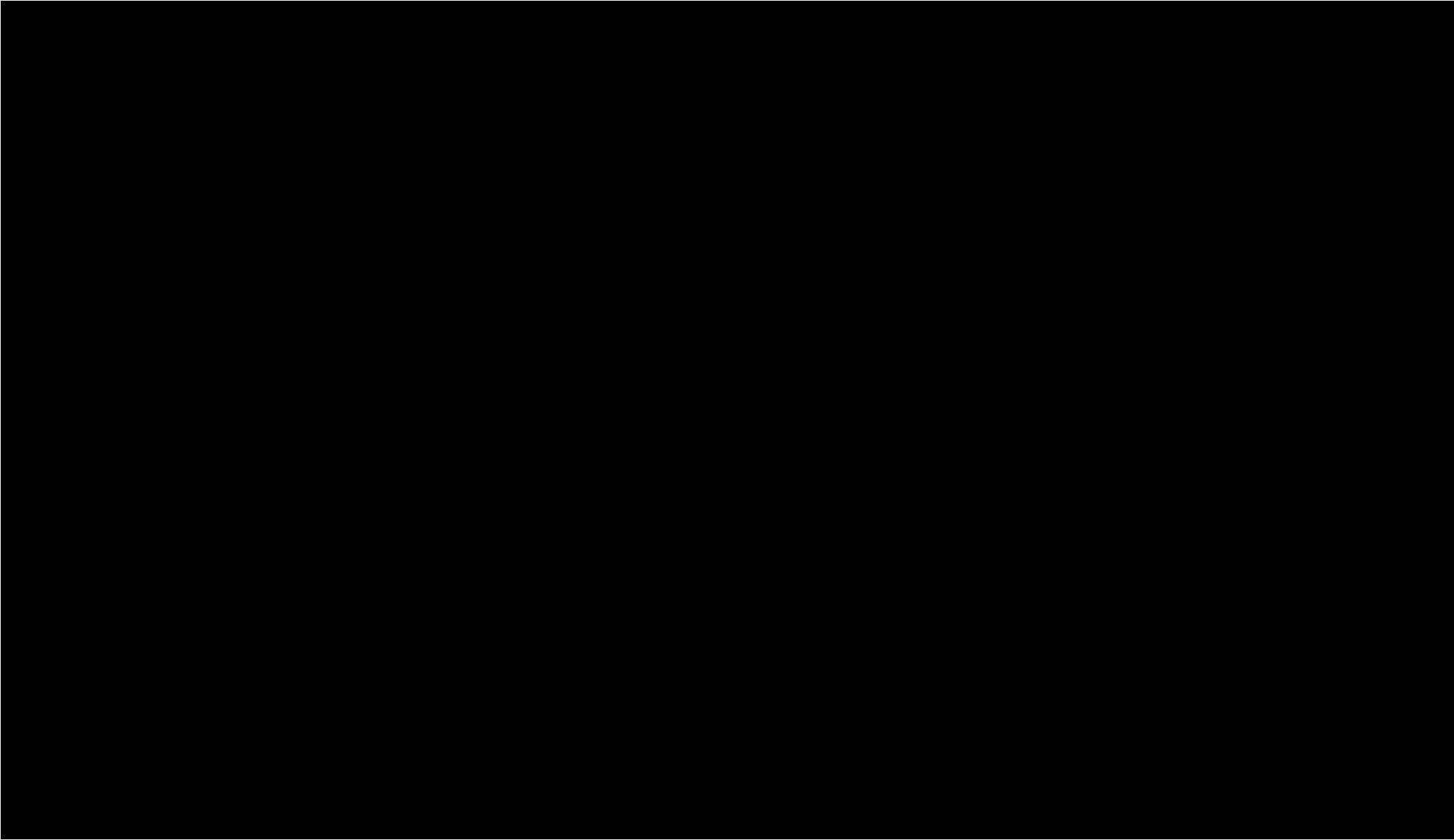


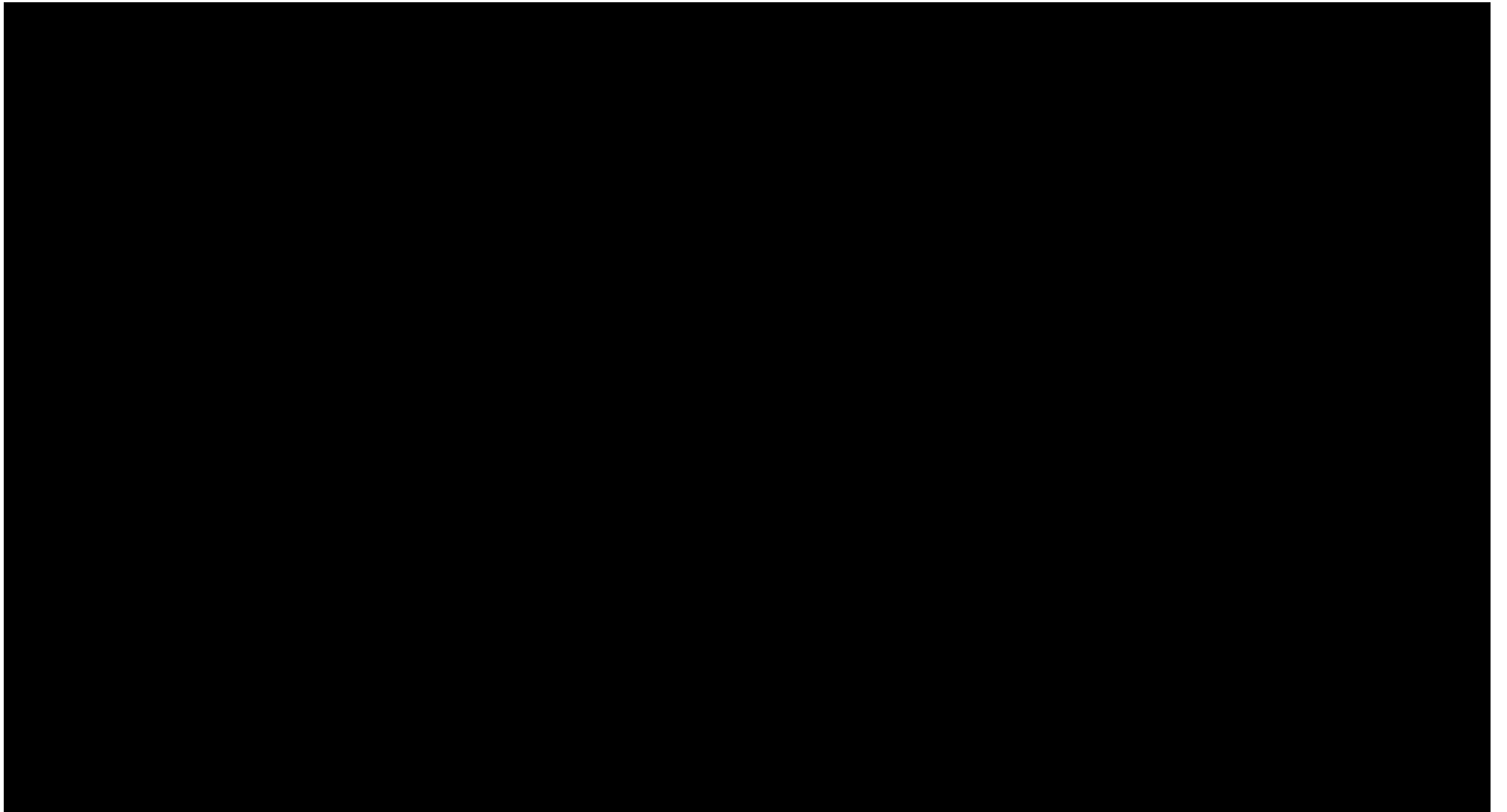
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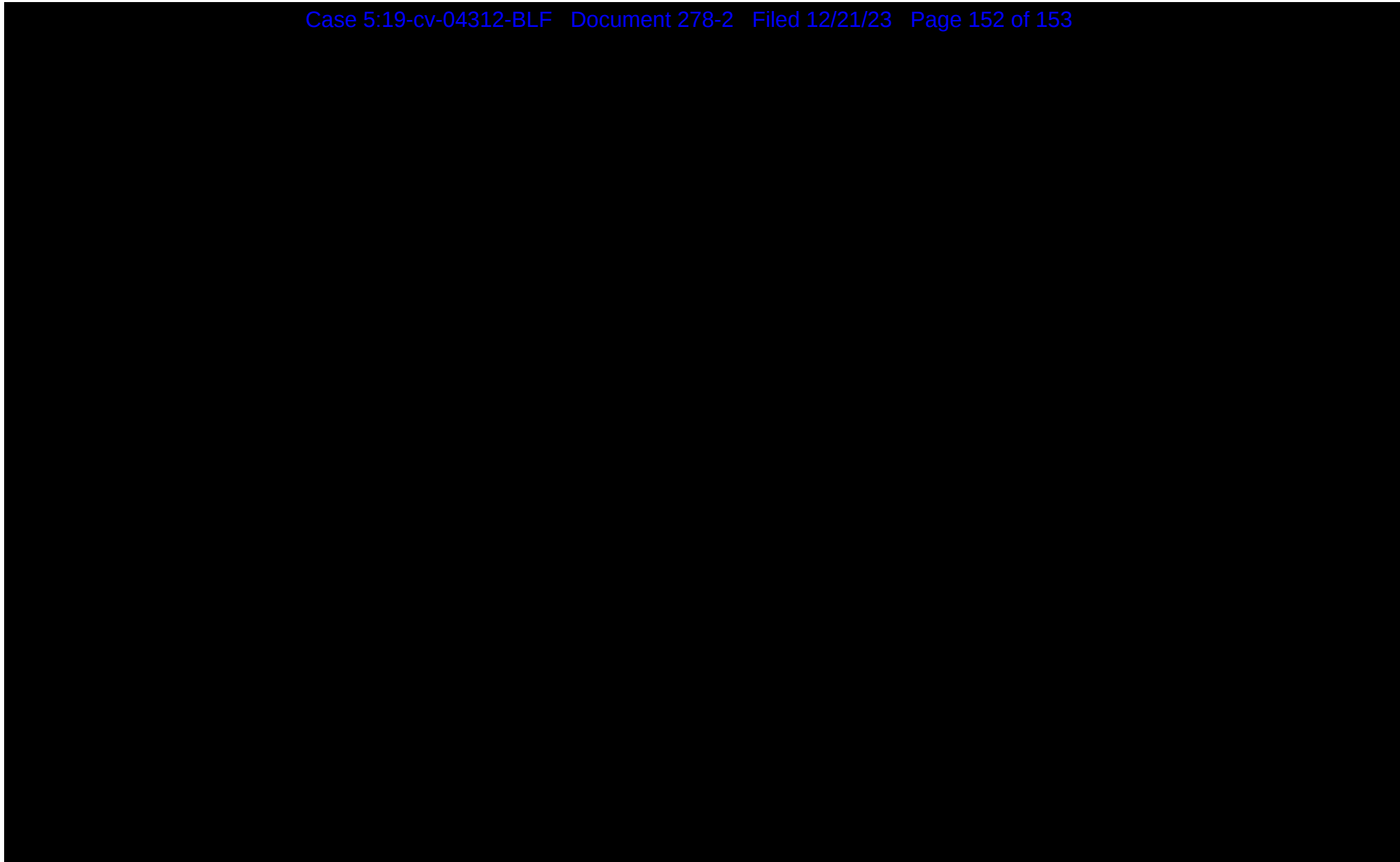
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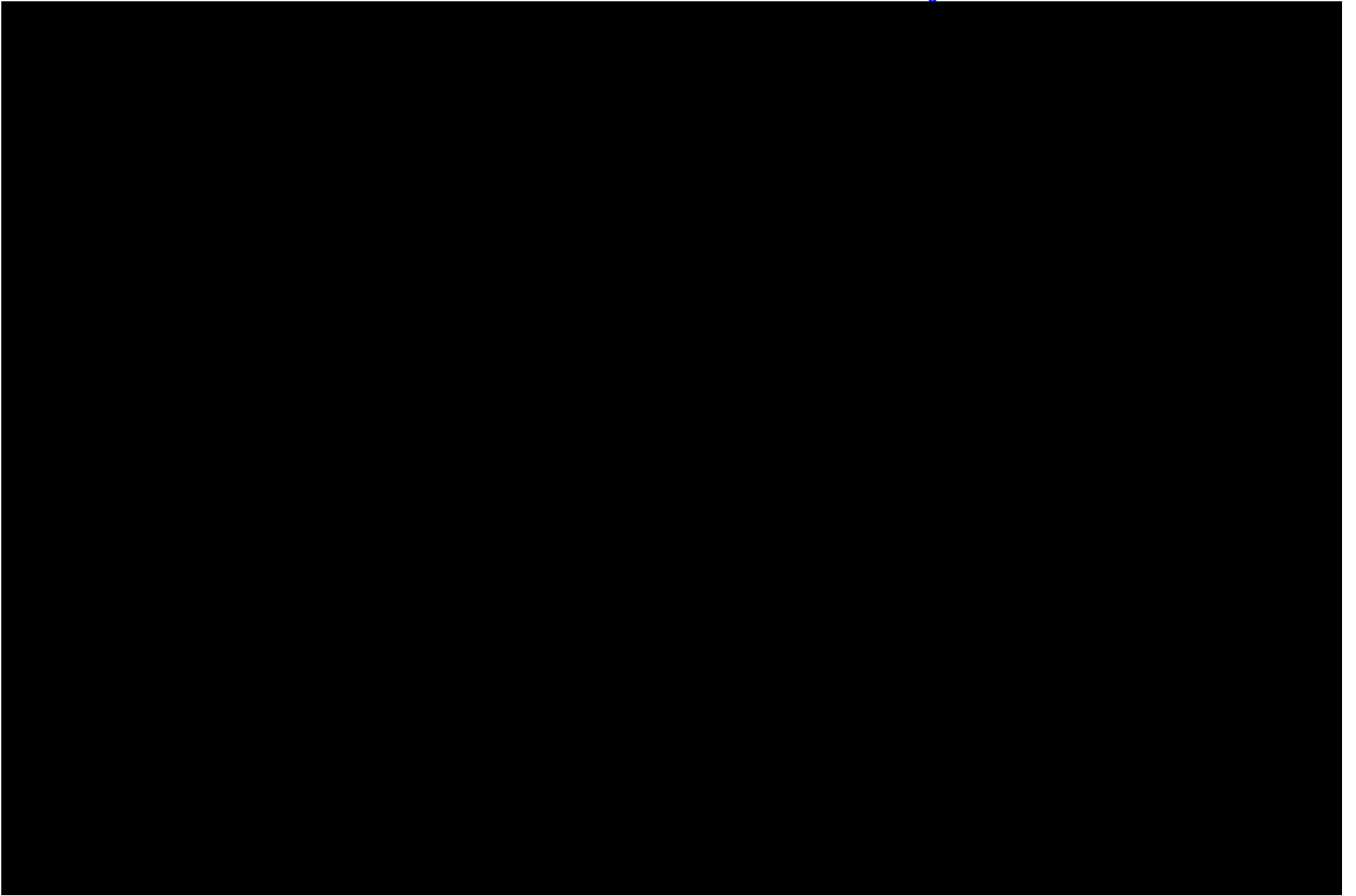




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